

Food and Drug Administration, HHS

§ 5.20

180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

(b) The Chief Counsel of the Food and Drug Administration, i.e., the Associate General Counsel in charge of the Food and Drug Division, has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Director, Office of Management, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the non-existence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has redelegated to the Commissioner of Food and Drugs appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(e) [Reserved]

(f) The Secretary of Health and Human Services has redelegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

[42 FR 15560, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.10, see the List of CFR

Sections Affected in the Finding Aids section of this volume.

§ 5.11 Reservation of authority.

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

[47 FR 16318, Apr. 16, 1982]

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart.

(b) The Deputy Commissioner and the Associate Commissioner for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs.

(c) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

(1) Deputy Commissioner.

(2) Associate Commissioner for Regulatory Affairs.

(3) Associate Commissioner for Management and Operations.

For a planned period of absence, the Commissioner may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him as “acting” or unless not legally permissible.

(e) The Deputy Commissioner for Operations is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and may be closed to the public in accordance with § 5.10(a)(18).

(f)(1) The Deputy Commissioner for Policy and the Associate Commissioner for Policy Coordination are authorized to perform any of the functions of the Commissioner of Food and Drugs with respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration.

(2) The Deputy Commissioner for Policy is authorized to issue responses to the following matters under part 10 of this chapter as follows:

(i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19;

(ii) Citizen petitions under § 10.30;

(iii) Petitions for reconsideration under § 10.33;

(iv) Petitions for stay under § 10.35; or

(v) Requests for advisory opinions under § 10.85.

(3) With respect to any matter delegated to the Deputy Commissioner for

Policy under this paragraph, the Deputy Commissioner for Policy is authorized to perform the functions of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 and of the Deputy Commissioner under § 10.206 (g) and (h) of this chapter.

(4) The Deputy Commissioner for Policy and the Associate Commissioner for Policy Coordination are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The delegation excludes the authority to submit reports to Congress.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices:

(1) Deputy Commissioner for Operations.

(2) Deputy Commissioner for Policy.

(3) Deputy Commissioner for External Affairs.

(4) Deputy Commissioner for Management and Systems.

(h) The Chief Mediator and Ombudsman is designated as User Fee Waiver Officer and is authorized to perform all of the functions of the Commissioner under the Prescription Drug User Fee Act of 1992 (21 U.S.C. 379h(d)), as amended hereafter, relating to the authority to waive or reduce user fees. The User Fee Waiver Officer’s authority may be redelegated to the Deputy Chief Mediator and Ombudsman and to the Deputy User Fee Waiver Officer without further redelegation. The Deputy Commissioner for Operations is designated User Fee Appeals Officer and 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.

(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]