

Food and Drug Administration, HHS

§5.11

the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(38) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101-629), as amended. The delegation excludes the authority to submit reports to Congress.

(39) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104-180), 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 re-delegated 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 of be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has re-delegated 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 re-delegated.

(e) [Reserved]

(f) The Secretary of Health and Human Services has re-delegated 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, which appears in the Finding Aids section of the printed volume and on GPO Access.

§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 following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs and this authority may not be further redelegated:

- (1) Deputy Commissioner;
- (2) Associate Commissioner for Regulatory Affairs;
- (3) Senior Associate Commissioner;
- (4) Deputy Commissioner for Management and Systems;
- (5) Senior Associate Commissioner for Policy, Planning, and Legislation; and
- (6) Deputy Commissioner for International and Constituent Relations.

(c)(1) 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:

- (i) Deputy Commissioner;
- (ii) Associate Commissioner for Regulatory Affairs; or
- (iii) Senior Associate Commissioner.

(2) This authority may not be further redelegated. However, for a planned period of absence, the Commissioner of Food and Drugs (or someone "acting" on his/her behalf) 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)(1) The Senior Associate Commissioner is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with §5.10(a)(18). This authority may not be further redelegated.

(2) The Senior Associate Commissioner is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees. This authority may not be further redelegated.

(3) The Senior Associate Commissioner is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended. This authority may not be further redelegated.

(4) The Senior Associate Commissioner is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center. This authority may not be further redelegated.

(f)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy 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. This authority may not be further redelegated.

(2) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to issue responses to the following matters under part 10 of this chapter as follows, and this authority may not be further redelegated:

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