

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;

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(ii) Citizen petitions under §10.30 of this chapter;

(iii) Petitions for reconsideration under §10.33 of this chapter;

(iv) Petitions for stay under §10.35 of this chapter; or

(v) Requests for advisory opinions under §10.85 of this chapter.

(3) With respect to any matter delegated to the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy under paragraph (f) of this section, the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to perform the function of the Commissioner of Food and Drugs under §§10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under §10.206(g) and (h) of this chapter. This authority may not be further redelegated.

(4) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy 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. This authority may be further redelegated.

(g) The following officials are authorized to perform all of the functions of the officials under them in their respective offices, and this authority may not be further redelegated:

(1) Senior Associate Commissioner;

(2) Deputy Commissioner for International and Constituent Relations;

(3) Deputy Commissioner for Management and Systems; or

(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions (under 21 U.S.C. 379h(d)) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. This authority may not be further redelegated. (See §5.101 for the user fee-related re-delegation to officials within the Center for Drug Evaluation and Research.)

(2) The Deputy Commissioner for Management and Systems and the Director, Office of Financial Management are authorized to perform the functions of the Commissioner under 21 U.S.C. 379h(d)(1)(C), as amended, to waive or reduce prescription drug user fees in situations where he/she finds that “the fees will exceed the anticipated present and future costs.” This authority may not be further redelegated.

(3) The Deputy Commissioner or, in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer 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. This authority may not be further redelegated.

(i) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under 35 U.S.C. 156(d)(2)(B)(ii), as amended, relative to patent term extensions. This authority may not be further redelegated.

(j) 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; 63 FR 41960, Aug. 6, 1998; 64 FR 59618, Nov. 3, 1999; 65 FR 34960, June 1, 2000]

§5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same