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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the general redelegations of authority from the Commissioner of Food and Drugs to other officers of FDA. On June 20, 1999, the Commissioner of Food and Drugs restructured FDA "to create a more streamlined and efficient Office of the Commissioner that will provide leadership without compromising programmatic effectiveness." In this restructuring, organizational components were abolished and established and functions and personnel were transferred. Therefore, FDA is updating the delegations of authority regulations to reflect these changes and to delegate authority to positions in newly established components. FDA is also updating some position titles that may have been affected by previous reorganizations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Donna G. Page, Division of Management Programs (HFA-330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority regulations in various sections of 21 CFR part 5, subpart B, *Redelegations of Authority from the Commissioner of Food and Drugs*, to reflect the most significant changes that resulted from the June 20, 1999, restructuring. (See 64 FR 36361 to 36368, July 6, 1999, and 64 FR 38675, July 19, 1999.) The

changes are as follows:

oc99190

NFR 1

a

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.20 is amended by revising paragraphs (b), (c), (e), (f), and (g); by redesignating paragraph (i) as paragraph (j); and by adding a new paragraph (i) to read as follows:

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

* * * * *

(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.

* * * * *

(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;

(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.

* * * * *

(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.

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3. Section 5.22 is amended by revising paragraphs (a)(1), (a)(2), (a)(3), (a)(6), (a)(7), (a)(10)(ii), (a)(11)(ii), (a)(12)(ii), (b)(1), (b)(2), and (b)(3); by redesignating paragraph (c) as paragraph (d) and revising newly redesignated paragraph (d); and by adding new paragraph (c) to read as follows:

§ 5.22 Certification of true copies and use of Department seal.

(a) * * *

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, and the Deputy Commissioner for Management and Systems.

(2) The Senior Associate Commissioners, the Associate and Deputy Associate Commissioners, and the Chief Counsel and Deputies.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

* * * * *

(6)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(7)(i) The Associate Commissioner for Public Affairs, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

(ii) The Director, Freedom of Information Staff, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

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(10) * * *

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

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(11) * * *

(ii) The Director and Deputy Director, Office of Management and Communications, CVM.

* * * * *

(12) * * *

(ii) The Director, Office of Management, Facilities, and Research Support, NCTR.

* * * * *

(b) * * *

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, and the Deputy Commissioner for Management and Systems.

(2) The Senior Associate Commissioners, the Associate and Deputy Associate Commissioners, and the Chief Counsel and Deputies.

(3) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(c) The authorities under § 5.22 (a) and (b), where appropriate, may be further redelegated by the Deputy Commissioners; Senior Associate Commissioners; Associate Commissioner for Regulatory Affairs and Deputy; Chief Counsel and Deputies; Center Directors and Deputies; and Executive Officers (i.e., Executive Assistant, Office of the Commissioner; Director, Office of Management, CBER; Director, Office of Management, CDER; Director, Office of Management and Systems, CFSAN; Director, Office of Systems and Management, CDRH; Director, Office of Management and Communications, CVM; Director, Office of Management, Facilities, and Research Support, NCTR; and the Director, Office of Resource Management, ORA).

(d) The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; Office of the Commissioner, and his/her alternates are authorized to certify true copies of **Federal Register** documents. The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; and the Office of the Commissioner may designate alternates as required.

4. Section 5.23 is amended by revising paragraphs (a)(1), (a)(2), (a)(4), and (d).

§ 5.23 Disclosure of official records.

(a) * * *

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, the Deputy Commissioner for Management and Systems, Senior Associate Commissioners, Associate and Deputy Associate Commissioners.

(2)(i) The Executive Assistant to the Commissioner, Office of the Commissioner.

(ii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

* * * * *

(4)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(ii) The Director, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Programs; Office of Human Resources and Management Services, Office of Management Services, Office of the Commissioner.

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(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office.

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5. Section 5.25 is amended by revising paragraphs (a)(7) and (c) to read as follows:

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) * * *

(7) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner.

* * * * *

(c) The Deputy Commissioner for Management and Systems, Office of Management and Systems, Office of the Commissioner; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services, Office of Management and Systems, Office of the Commissioner; the Director, Division of Contracts and Procurement Management, Office of Facilities, Acquisitions, and Central Services, Office of Management and Systems, Office of the Commissioner; and the Chief Grants Management Officer and the Grants Management Officer, Division of Contracts and Procurement Management, Office of Facilities, Acquisitions, and Central Services, Office of Management Systems, Office of the Commissioner 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.

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6. Section 5.27 is revised to read as follows:

§ 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).

7. Section 5.30 is amended by revising paragraph (c)(1) to read as follows:

§ 5.30 Hearings.

* * * * *

(c) * * *

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner.

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8. Section 5.32 is revised to read as follows:

§ 5.32 Authority relating to determination of product classification and assignment of primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) respecting the classification of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act, and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product.

9. Section 5.34 is amended by revising paragraph (a) to read as follows:

§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or the Senior Associate Commissioner, Office of the Commissioner.

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10. Section 5.58 is amended by revising introductory text of paragraphs (a) and (b) to read as follows:

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

* * * * *

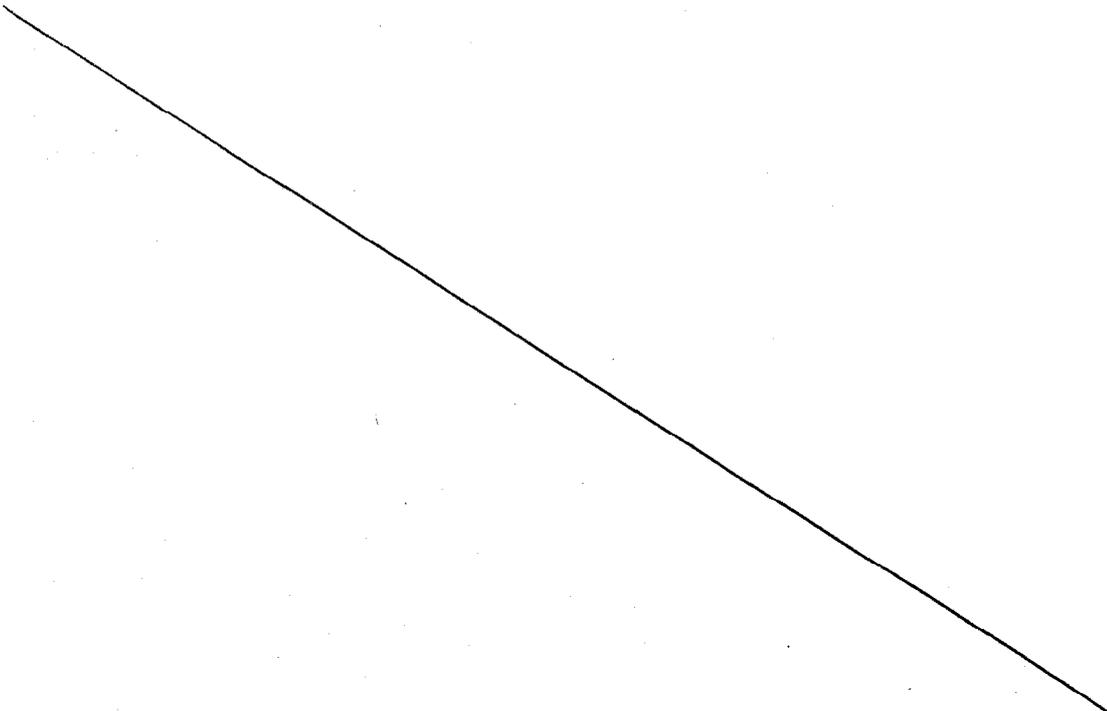
(b) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized:

* * * * *

11. Section 5.81 is revised to read as follows:

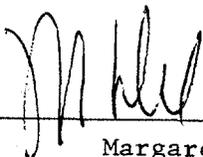
§ 5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Director, Center for Drug Evaluation and Research (CDER) and the Director, Executive Operations Staff, Office of the Center Director, CDER are authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970,



21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress. Further redelegation may only be authorized with the Commissioner of Food and Drugs' approval.

Dated: 5/17/00
May 17, 2000



Margaret M. Dotzel,
Acting Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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