Accreditation Program (NVLAP) operates as an unbiased third party to accredit both calibration laboratories and testing laboratories. NVLAP accredits laboratories in response to (a) mandates by the Federal Government; (b) requests from a government agency; and (c) requests from a private sector organization.

The NVLAP procedures were first published in the **Federal Register** on February 25, 1976, and have been revised several times since then. Certain authorities under the NVLAP regulations were given to the Director of NIST. In accordance with 15 CFR subpart A, section 285.5, the Director of NIST delegated these authorities to the Chief of the National Voluntary Laboratory Accreditation Program on February 20, 1996, in a memorandum to the Director of the Office of Standards Services. The delegation of authority was not extended to the conclusion of any agreements with the governments of other countries referenced in Section 285.11(f) of Title 15 of the Code of Federal Regulations.

Purpose

The purpose of this rule is to amend Part 285 of Title 15 of the CFR so that it conforms to the current delegation of authority.

Rulemaking Requirements

Under Title 5 United States Code Section 553, this rule is not subject to the notice and comment requirements of the Administrative Procedure Act. This rule only relates to Agency organization, management or personnel (5 USC 553 (a)(2)).

PRA Clearance. This rule does not contain a collection of information for purposes of the Paperwork Reduction Act.

Executive Order 12866: This rule is exempt under Section 3(d)(3) of E.O. 12866.

Regulatory Flexibility Act. This action is exempt from the analytical requirements of the Regulatory Flexibility Act because notice and comment are not required for this action by Section 553 of the Administrative Procedure Act or any other law.

List of Subjects in 15 CFR Part 285

Business and industry, Commerce, Laboratories, Measurement standards.

Dated: October 26, 1999.

Karen H. Brown,

Deputy Director.

For the reasons set forth in the preamble, Title 15 of the Code of Federal Regulations (CFR), part 285 is amended as follows:

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

1. The authority citation for 15 CFR part 285 continues to read as follows:

Authority: 15 U.S.C. 272 et seq.

§ 285.3 [Amended]

2. In § 285.3(c) remove the phrase, ''Director of the National Institute of Standards and Technology (NIST)'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.11 [Amended]

3. In § 285.11 (a) and (d) introductory text, remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

4. In § 285.11(e) introductory text, remove the phrase, ''Director'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.12 [Amended]

5. In § 285.12(a) introductory text, (b) introductory text (twice), (c), (d), and (e), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.13 [Amended]

6. In 285.13 (a) and (d), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.14 [Amended]

7. In § 285.14(a) introductory text and (d), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.19 [Amended]

8. In § 285.19(a) (twice) and (c) (twice), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NLAP.''

[FR Doc. 99–28665 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner and the Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the delegations of authority statement that covers general redelegations of authority from the Commissioner of Food and Drugs to other officers of FDA. The amendment delegates authority to perform all functions relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992 (PDUFA), as originally enacted and as reauthorized by the FDA Modernization Act of 1997 (the Modernization Act), to the Director, Center for Drug Evaluation and Research (CDER) and to the Associate Director for Policy, CDER, except for the functions that pertain to situations where ''the fees will exceed the anticipated present and future costs.'' The authority to waive or reduce user fees, previously redelegated to the Chief Mediator and Ombudsman/User Fee Waiver Officer, the Deputy Chief Mediator and Ombudsman, and the Deputy User Fee Waiver Officer is hereby revoked, except the authority to act upon requests for reconsideration of any user fee decision made by such officers prior to July 1, 1999. Also, as a result of the June 20, 1999, FDA reorganization, the Office of Operations component and the Deputy Commissioner for Operations position were abolished; therefore, the Deputy Commissioner will assume the role of the User Fee Appeals Officer and perform the associated functions.

EFFECTIVE DATE: July 1, 1999.

ADDRESSES: As of July 1, 1999, submit all requests for waivers, refunds, and reductions in user fees under PDUFA, originally enacted and reauthorized by the Modernization Act, to the Associate Director for Policy, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Attn: User Fee Waiver Office. Submit requests sent via a courier that requires a street address to the Associate Director for Policy, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, Attn: User Fee Waiver Office. Submit requests for reconsideration of user fee waiver determinations made prior to the effective date of this document to the Office of the Chief Mediator and Ombudsman, (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Beverly J. Friedman, User Fee Staff (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or

Donna G. Page, Division of Management Programs (HFA–340),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority under § 5.20 *General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration* (21 CFR 5.20) by revising § 5.20(h) to revoke the authority of the Chief Mediator and Ombudsman/User Fee Waiver Officer, the Deputy Chief Mediator and Ombudsman, and the Deputy User Fee Waiver Officer to waive or reduce user fees under the waiver provisions of PDUFA as originally enacted and as amended by the Modernization Act (section 736(d) and (a)(1)(G) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d) and (a)(1)(G)), except the authority to act upon requests for reconsideration of any user fee decision made by such officers prior to July 1, 1999. FDA is also revising the section to reflect that the Deputy Commissioner is designated as the User Fee Appeals Officer and in the case of a vacancy in the position, to reflect the designation of the Senior Associate Commissioner, Office of the Commissioner as the User Fee Appeals Officer.

FDA is adding § 5.101 *Authority relating to waivers or reductions of prescription drug user fees* to reflect redelegation of certain user fee-related authorities under section 736(d) and (a)(1)(G) of the act, as amended, to the Director, CDER and to the Associate Director for Policy, CDER. CDER will exercise the authority now being delegated to resolve requests for waivers, reductions, or refunds of assessable fees relating to human drug products reviewed and regulated by CDER, the Center for Biologics Evaluation and Research, and any other FDA center.

Authority delegated to a position by title may be exercised by a person officially designated to serve in such a position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as ''acting'' or unless not legally permissible. These authorities may not be further redelegated.

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 paragraph (h) to read as follows:

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

* * * * *

(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 redelegation 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.

3. Section 5.101 is added to subpart C to read as follows:

§ 5.101 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Policy, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of l992, as originally enacted and as reauthorized by the FDA Modernization Act of l997, except for the functions under 21 U.S.C. 379h(d)(1)(C) that pertain to situations where ''the fees will exceed the anticipated present and future costs,'' on behalf of CDER, the Center for Biologics Evaluation and Research, and any other FDA center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. These authorities may not be further redelegated. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.)

* * * * *

Dated: October 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28562 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N–2550]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. This amendment is being made in order that manufacturers may use state-of-the-art methods to address technical data in hearing aid labeling. FDA is amending