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Ombudsman, and the Deputy User Fee Waiver Officer to waive or reduce user fees under the waiver provisions of PDUFA as originally enacted and as amended by the Modernization Act (section 736(d) and (a)(1)(G) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d) and (a)(1)(G)), except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

the regulations in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws this direct final rule.

DATES: This regulation is effective March 17, 2000. Submit written comments on or before January 17, 2000. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 801.420(c)(4) (21 CFR 801.420(c)(4)), effective March 17, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ–460), Food And Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 15, 1977 (42 FR 9286), FDA published final regulations establishing requirements for professional and patient labeling of hearing aids (§ 801.420) and governing conditions for sale of hearing aids (§ 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the regulations provides that, before the sale of a hearing aid to a prospective user, a hearing aid dispenser is to provide the prospective user with a copy of the User Instructional Brochure. Section 801.420(c)(4) requires that technical data useful in selecting, fitting, and checking the performance of a hearing aid be provided in the brochure or in separate labeling that accompanies the device. The regulation further required that the technical data values provided in the brochure or other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the ''American National Standard Specification of Hearing Aid Characteristics,'' ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation.

ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several definitive hearing aid characteristics, and provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.

In 1982, ASA revised the standard (ANSI S3.22–1982) (ASA 70–1982). In a final rule published in the **Federal Register** of July 24, 1985 (50 FR 30153). FDA incorporated the revised standard into § 801.420(c)(4). ASA revised the standard again in 1987 (ANSI S3.22–1987) (ASA 70–1987). In a final rule published in the **Federal Register** of December 21, 1989 (54 FR 52395), FDA incorporated the newly revised standard into § 801.420(c)(4).

In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). The standard describes air-conduction hearing aid measurement methods that are particularly suitable for specification and tolerance purposes. Among the test methods described are output sound pressure level (SPL with a 90-dB input SPL, full-on gain, frequency response, harmonic distortion, equivalent input noise, current drain, induction-coil sensitivity, and static and dynamic characteristics of automatic gain control hearing aids. The standard gives specific configurations for measuring the input SPL to a hearing aid. The standard also describes allowable tolerances in relation to values specified by the manufacturer for certain parameters. Appendices are provided to describe an equivalent substitution method, characteristics of battery simulators, and additional tests to characterize the electroacoustic performance of hearing aids more completely.

FDA is now incorporating the 1996 standard into § 801.420(c)(4). This will allow hearing aid manufacturers to use the up-to-date methods to determine the technical data values for hearing aids. In addition, FDA is removing from § 801.420(c)(4) the address for ''American National Standard Institute'' and is adding in its place the address for ''Acoustical Society of America.''

II. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend part 801 (21 CFR part 801). The companion proposed rule and the direct final rule are substantively identical. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of a significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments to the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule until January 17, 2000. If the agency receives a significant adverse comment, FDA intends to withdraw this final rule by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment requesting a change in provisions of the hearing aid rule unrelated to the subject matter addressed in the ANSI standard will not be considered a significant adverse comment, because it is outside the scope of the rule. On the other hand, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be

severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the proposed rule in developing a final rule in accordance with usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation document within 30 days after the comment period ends confirming the effective date.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impact of this direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The direct final rule amends the existing hearing aid regulation to refer to the updated consensus standard that is used to determine the technical data in hearing aid labeling. Communications from manufacturers to FDA show that they are prepared to be in compliance with this standard immediately. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

V. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is no required.

VI. Request for Comments

Interested persons may, on or before January 17, 2000, submit to the Docket Management Branch (address above) written comments regarding this direct final rule. The comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the companion proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and this direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 801

Hearing aids, Incorporation by reference, Medical devices, Professional and patient labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority section for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. Section 801.420 is amended by revising the second and third sentences in paragraph (c)(4) to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(c) * * *

(4) * * * The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996) (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 240, Rockville, MD 20850, and at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. * * *

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Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28209 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 982

[Docket No. FR–4428–F–05]

RIN 2577–AB91

Housing Choice Voucher Program; Amendment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: On October 21, 1999, HUD published a final rule implementing the statutory merger of the Section 8 tenant-based certificate and voucher programs. This rule makes an amendment to the October 21, 1998 final rule concerning the 40 percent of adjusted monthly income initial rent burden limit. HUD is making this change based upon its reconsideration of the statutory language and legislative history regarding this requirement.

DATES: Effective Date: December 3, 1999.

FOR FURTHER INFORMATION CONTACT: Gerald J. Benoit, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4210, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–0477. (This is not a toll-free number.) Hearing or speech-impaired individuals may access this number via TTY by calling