DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2607]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 22, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control No. 0910–0171—Extension)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801.421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting, fitting, and checking the performance of a hearing aid through distribution of a user instructional brochure. The user instructional brochure must also contain technical data about the device, instructions for its use, maintenance and care, a warning statement, a notice about the medical evaluation requirement, and a statement if the aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the user instructional brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the user instructional brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a user instructional brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the user instructional brochure to sellers for distribution to users and prospective users and provide a copy of the user instructional brochure to any health care professional, user, or prospective users who request a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by signing a written statement. Finally, the regulation requires that the dispenser retain for 3 years copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the user instructional brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.

The respondents to this collection of information are hearing aid manufacturers, distributors, dispensers, health care professionals, or other for-profit organizations.

In the **Federal Register** of August 25, 1999 (64 FR 46395), the agency requested comments on the proposed collection of information.

FDA received one comment from an association representing hearing aid manufacturers. The comment noted that the association had commented in 1998 on this collection of information and had suggested through a limited survey of its members that its companies produced 18 models and not the 5 estimated by FDA and that it took 136 hours for a company to prepare a User Instructional Brochure. The comment noted that FDA used a figure of 102 hours and failed to address where this figure came from.

FDA previously addressed this comment in the **Federal Register** of October 26, 1998 (63 FR 57128). FDA agreed with the comment with respect to the number of models, and FDA raised its estimate in that respect. FDA noted, however, that the comment failed to take into account that FDA was estimating an annual burden and not every model required a new brochure every year. FDA further noted that much of the information in the brochure remains the same from one permutation of a model to another and, therefore, it would not take 136 hours to develop every brochure. FDA estimated that, for about half of the models, it would only take one-half of 136 hours or 68 hours to modify the brochure. From this, FDA estimated that the average preparation time for all brochures would be 102 hours. FDA believes that this estimate is still appropriate.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.420(c)	40	24	960	102	97,920
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,900	5	49,700	0.17	8,449
Total					586,369

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	162	1,600,000	0.25	400,000
Total					400,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 801.420(c) estimate assumes that 40 hearing aid manufacturers or distributors each will distribute 5 different models of hearing aids. Thus, the 40 hearing aid manufacturers or distributors will provide 5 different user instructional brochures to sellers for distribution to prospective users and users. The completion of each user instructional brochure is estimated to require 102 staff hours.

Section 801.421(b) estimate assumes that 9,900 hearing aid dispensers will have 162 sales annually. For all such sales, the dispenser must provide the prospective user a copy of the user instructional brochure and the opportunity to read and review the contents with him or her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

Section 801.421(c) estimate assumes that 40 hearing aid manufacturers or distributors and 9,900 dispensers will provide copies of the user instructional brochure to any health care professional, user, or prospective user who requests a copy in writing. It is estimated that five written requests for copies of the brochures will be received by each hearing aid manufacturer or distributor and dispenser annually. It is estimated that each request for a brochure will take .17 staff hours to complete. This effort consists of the hearing aid manufacturer or distributor or hearing aid dispenser locating the appropriate user instructional brochure for the specific model and mailing the brochure to the requester.

Section 801.421(d) recordkeeping estimate assumes that 9,900 hearing aid dispensers will each retain 162 records. Each record documents the dispensing of a hearing aid to a hearing aid user. The recordkeeping entry is estimated to require 0.25 staff hours.

Dated: November 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

Reuse of Single Use Devices; FDA's Proposed Strategy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Reuse of Single Use Devices—FDA's Proposed Strategy. The topic to be discussed is the current practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use and FDA's proposed strategy to address concerns regarding this practice.

Date and Time: The meeting will be held on December 14, 1999, 8 a.m. to 5:30 p.m.

Location: The meeting will be held at the University of Maryland Auditorium, 9640 Gudelsky Dr., Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Heather Howell, Center for Devices and Radiological Health (HFZ–205), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD, 20850, 301–594–3252, FAX 301–443–7185, Internet site: http://www.fda.gov/cdrh/reuse, e-mail: reuse@cdrh.fda.gov.

Registration and Requests for Oral Presentations: Please register online on the Internet at http://www.fda.gov/cdrh/reuse by December 1, 1999. There is no charge to attend this meeting, but advance registration is requested due to limited seating. Those desiring to make formal oral presentations should submit a brief statement of the general nature of their presentation, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation. The time allotted for each presentation is limited.

Written comments may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by December 1, 1999.

If you need special accommodations due to a disability, please contact Heather Howell at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the availability of a document entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' in the **Federal Register** of November 3, 1999 (64 FR 59782). The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use. The agency is interested in discussing this proposed strategy, and it is soliciting comments, proposals for alternative approaches, and information on this issue.

II. Electronic Access

In order to receive ''FDA's Proposed Strategy on Reuse of Single Use