comments and suggestions submitted within 60 days of this publication.

Dated: March 3, 1997.

Bob Sargis,

*Acting Reports Clearance Officer*

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## Food and Drug Administration

**[Docket No. 97N–0022]**

## Agency Information Collection Activities: Proposed Collection; Reinstatements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the Federal Register concerning each collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements relating to the manufacture and distribution of hearing aid devices, reporting requirements for firms that provide electronic product samples to FDA for research and testing purposes, reporting requirements for firms that intend to export certain unapproved medical devices, and reporting and recordkeeping requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further process labeling or repacking.

**DATES:** Submit written comments on the collection of information requirements by May 6, 1997.

**ADDRESSES:** Submit written comments on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to the following collections of information, FDA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burdens of the proposed collections of information, including the validity of the methodologies and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burdens of the collections of information on respondents, including through the use of appropriate automated collection techniques, when appropriate, and other forms of information technology.

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

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services (the Secretary) 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 requests 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 professionals, or other for profit organizations.

On September 29, 1993, FDA conducted an audit of hearing aid dispensers in four FDA districts to determine the level of compliance with existing hearing aid requirements. The estimates relating to §§ 801.421(a)(1) and 801.420(a)(2) in the reporting and recordkeeping burden tables below are based on information obtained in this audit. This audit revealed that medical evaluations were obtained in 32 percent of the sales and signed waivers were obtained in 60 percent of the sales.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 801.420(c) | 40 | 5 | 200 | 40 | 8,000 |
| 801.421(a)(1) | 9,900 | 52 | 514,800 | 0.10 | 51,480 |
| 801.421(a)(2) | 9,900 | 97 | 960,300 | 0.30 | 288,090 |
| 801.421(b) | 9,900 | 162 | 1,600,000 | 0.30 | 480,000 |
| 801.421(c) | 9,940 | 5 | 49,700 | 0.17 | 8,449 |
| Total Burden Hours | | | | | 836,019 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

| 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 |

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

2. Notice of Availability of Sample Electronic Product—21 CFR Parts 1020, 1030, 1040, and 1050 and FDA Form 2767 (OMB Control No. 0910–0048—Reinstatement)

Under sections 532 to 542 of the act (21 U.S.C. 360ii to ss), FDA is authorized to protect the public from unnecessary exposure to radiation from electronic products. Section 532 of the act directs the Secretary to establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic radiation, and authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products.

The Center for Devices and Radiological Health (CDRH) conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050 (21 CFR parts 1020, 1030, 1040, and 1050). The ''Notice of Availability of Sample Electronic Product''(Form FDA 2767) is used to inform CDRH of the location of sample products that are being requested for testing to confirm that the products comply with performance standards. Form FDA 2767 is a summary form which reports information required by parts 1020, 1030, 1040, and 1050.

FDA also uses this information to locate and select sample products to ensure conformance with regulations. In the event this information were not collected by CDRH, each manufacturer would have to respond in letter format with all the data now being recorded on Form FDA 2767, which would require more time and expense. Testing an appropriate percentage of these products to protect the public would also be hindered by the slower process.

The respondents to this collection of information are manufacturers of electronic products.

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

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Part and Form Number | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 1020, 1030, 1040, 1050, and Form FDA 2767 | 145 | 11.03 | 1,600 | 0.09 | 144 |
| Totals | | | | | 144 |

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

FDA's estimates are based on actual data collected from industry over the past 3 years, where there has been an average of 1,600 annual responses to FDA from 145 respondents each year.

3. Export of Medical Devices—Foreign Letters of Approval—21 U.S.C. 381(e)(2) (OMB Control No. 0910–0264—Reinstatement)

Section 801(e)(2) of the act (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device.

The written authorization from the foreign country is used by the Office of Compliance, CDRH in determining if the foreign country has any objection to the importation of the device into their country. In FY 95, the Office of Compliance received approximately 800 requests from U.S. firms to export medical devices under section 801(e)(2) of the act. If approval letters from foreign governments were not submitted by the requesting firm, CDRH would then have had to contact various embassies (via telephone, for example) to seek their approval, which would have been time consuming and costly.

The respondents to this collection of information are companies that seek to export medical devices.

The foreign letters of approval are submitted under a statutory information collection requirement only. Because there is no additional burden attributable to a regulation, no burden chart is included.

4. Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(a)(2) and (e) (OMB Control No. 0910–0131—Reinstatement)

Under sections 501(c) and 502(a) of the act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(a)(2) and (e) (21 CFR 801.150(a)(2) and (e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(a)(2) and (e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. To discontinue this reporting and recordkeeping procedure would place an economic hardship on the industry and an additional burden on FDA to monitor product in interstate commerce for failure to comply with adulteration and misbranding provisions of the act.

The respondents to this collection of information are device manufacturers and contract sterilizers.

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

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 801.150 | 90 | 20 | 1,800 | 4 | 7,200 |

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

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

Dated: February 25, 1997.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

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## Health Resources and Services Administration

## Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.