

**SUPPORTING STATEMENT
FOR
Hearing Aid Devices, Professional and Patient Labeling and Conditions for Sale
21 CFR 801.420 and 801.421
OMB No. 0910-0171**

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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. Section 502(q) of the act (21 U.S.C. 352(q)) provides that a restricted device shall be deemed to be misbranded if (1) its advertising is false or misleading in any particular, or is sold, distributed, or used in violation of the regulations prescribed under section 520(e). Section 704(a) of the act (21 U.S.C. 374(a)) authorizes FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any facilities where restricted devices are manufactured, processed, packed, or held, and provides that the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities).

The U.S. Food and Drug Administration (FDA) was granted a one year approval for this information collection on November 26, 1997 on the condition that the Agency would: (1) draft a detailed response to the comments received for the file and provide the response by December 7, 1997 (Attachment A) and (2) provide the Office of Management and Budget (OMB) a detailed status of the hearing aid rule under consideration at FDA with specific reference to how the regulations could be updated to reduce the reporting burden while still maintaining the safety and efficacy of the product, and explanation for any delays in proceeding with this rulemaking.

Communication has been ongoing with representatives from the industries affected. In the Federal Register of November 10, 1993, FDA published an ANPRM (Attachment B) announcing its intention to review the current hearing aid regulation. Public hearings on the issues raised in the ANPRM were held on December 6, and December 7, 1993. FDA received more than 3,000 comments from manufacturers, physicians, audiologists, hearing aid dispensers, professional organizations, consumer interest groups, educational institutions, state governments, state professional organizations, and state licensing boards in response to the meeting and the ANPRM, and met with many groups representing various constituencies affected by the rule.

On February, 15, 1977, FDA established uniform professional and patient labeling requirements and conditions for sale of hearing aid devices. The regulations set forth the types of information that must be included in the labeling to provide hearing health professionals and patients with adequate directions for the safe and effective use of a hearing aid; specified the technical performance data that must be included in the labeling to ensure that the hearing health professional has adequate information to select, fit, and repair a hearing aid for a patient; and restricted the sale of a hearing aid to those patients who have undergone a

medical evaluation within the past 6 months, unless a fully informed adult patient waived the medical evaluation because of personal or religious beliefs.

The FDA is working towards completion of a Hearing Aid Rule which, when the information collection provisions are approved by OMB, will replace this information collection. The proposed hearing aid rule would eliminate physician's statements and waiver statements and replace them with a system in which the States would determine the types of health professionals able to perform proper testing before a hearing aid sale. Recordkeeping would generally be limited to records of hearing testing that would have already been kept in the ordinary course of business of hearing health professionals, so no additional recordkeeping burden is anticipated. The rule should be at OMB in early fall, 1998.

The proposed Hearing Aid Rule is currently under review by the Department of Health and Human Services (DHHS) prior to it being sent to OMB for review. In addition to reviewing the comments and preparing the proposal for this rule, FDA had to prepare substantial assessments under E.O. 12866, the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Unfunded Mandates Act. Because of the impact this proposed rule will have on all States, FDA made a substantial effort to obtain input on this rule from all 50 States plus the District of Columbia. During this process, the Regulatory Flexibility Act was amended in 1995, requiring FDA to revise their assessment to meet the requirements of that statute. The rule was further delayed by the need to survey the States in order to perform a Federalism Assessment under E.O. 12612. The latest delay in the rule was caused by the need to determine its effect on the Health Care Financing Administration's (HCFA's) reimbursement for hearing testing. A resolution to this problem has been made and has been incorporated into the preamble.

It is anticipated that the proposed Hearing Aid Rule will not be ready by the time of expiration of this information collection on November 30, 1998; therefore, the FDA is requesting approval from OMB for an extension of the collection of information from the public associated with hearing aids as indicated in 21 CFR 801.420 (c) and 21 CFR 801.421(a)(b)(c) and (d).

The following is a description of information collection requirements in Sections 21 CFR 801.420 (c) and 21 CFR 801.421(a)(b)(c) and (d) (Attachment C).

21 CFR 801.420(c)(1) Disclosure/Notification - Section 801.420(c)(1), "Labeling Requirements for Hearing Aids - General", -- requires that the manufacturer or distributor of the hearing aid develop a User Instructional Brochure which accompanies the device and is provided to the prospective user by the dispenser of the hearing aid. The Brochure shall contain the following information and instructions for use to the extent applicable:

- (I) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.
- (ii) Information on the function of all controls intended for user adjustment.
- (iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.
- (iv) Specific instructions for use, maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time. In addition,

instructions regarding replacing or recharging the batteries including a generic designation of replacement batteries.

- (v) Information on how and where to obtain repair service.
- (vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.
- (vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician.
- (viii) A statement that the hearing aid will not restore normal hearing or improve a hearing impairment resulting from organic conditions.
- (ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.
- (x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip-reading.
- (xi) Warning statement as required by paragraph (c)(2) of 801.420.
- (xii) The notice for prospective hearing aid users required by paragraph (c)(3) of 801.420.
- (xiii) The technical data required by paragraph (c)(4) of 801.420, unless such data is provided in separate labeling accompanying the device.

21 CFR 801.420 (c)(4) Disclosure/Notification - requires that technical data useful in selecting, fitting and checking the performance of a hearing aid be provided in the User Instructional Brochure or in a separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted using the test procedures of the American National Standard "Specification of Hearing Aid Characteristics", ANSI S3.22-1987 (ASA 70 - 1987)(Revision of S3.22-1982), as a reference method. As a minimum, the User Instructional Brochure or other such labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in the standard:

- (I) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

21 CFR 801.421(a)(1) Disclosure/Notification - Medical evaluation requirements-General-Requires a written statement signed by a licensed physician that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid before a hearing aid can be dispensed. The evaluation must have taken place within the preceding 6 months.

21 CFR 801.421(a)(2) Disclosure/Notification - Waiver to the medical evaluation requirements- permits a prospective user who is eighteen years or older, to forgo the medical evaluation described in paragraph 801.421(a)(1), provided the dispenser:

- (I) Informs the prospective user that to use the waiver is not in the user's best health interest.
- (ii) Does not in any way encourage use of the waiver, and
- (iii) Provides waiver statement for the prospective user to sign.

Section 801.421(b) Disclosure/Notification - Opportunity to review User Instructional Brochure - Hearing aid dispenser provides the prospective user a copy of the User Instructional Brochure and the opportunity to review the contents with him/her orally, or in the predominant method used during the sale, and affords the prospective user an opportunity to read the brochure.

21 CFR Section 801.421(c) Disclosure/Notification - Availability of User Instructional Brochure - upon request by a prospective purchaser of a hearing aid, requires the dispenser, with respect to any hearing aid that he dispenses, to provide a copy of the User Instructional Brochure or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

21 CFR 801.421(d) Recordkeeping - Requires the dispenser to retain for three years from time of dispensing, copies of all physician statements or any waivers of medical evaluation.

2. Purpose and Use of the Information

The technical information to be contained in the User Instructional Brochure or in separate labeling is intended not only for the hearing aid user but also the physician, audiologist, and dispenser. The information is useful when repairing a hearing aid or in evaluating the appropriateness of the hearing aid to be fitted. 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 user. The medical evaluation by the physician is in the patient's best health interest because it will help to determine the cause of, and the pathology associated with, the patient's hearing loss. The waiver demonstrates that a fully informed adult has waived the medical evaluation requirement.

3. Use of Information Technology and Burden Reduction

Manufacturers and/or dispensers may use any appropriate technology to develop, maintain, and/or disseminate the required User Instructional Brochure or separate labeling, and medical evaluation or waiver. Utilization of computers and word processors have greatly reduced the time needed to compile, submit, and maintain the required documents.

4. Efforts to Identify Duplication and Use of Similar Information

The Food and Drug Administration is the only agency responsible for the collection of such information, and charged with the responsibility of regulating establishments that manufacture medical devices for

introduction into interstate commerce. Therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

The FDA has established a Division of Small Manufacturers Assistance (DSMA) as required by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. DSMA provides technical and nonfinancial assistance to firms through a comprehensive program, which includes onsite inspections, seminars and educational conferences, informational materials and use of a toll-free number which may be used by firms that require information or assistance. Additional Center for Devices and Radiological Health staff are available for consultation on request.

6. Consequences of Collecting the Information Less Frequently

If technical information were not collected and provided in the User Instructional Brochure or separate labeling, FDA could not sufficiently protect the health of the hearing impaired by ensuring that physicians, audiologists and dispensers are adequately informed when fitting and/or repairing hearing aids.

There are no technical and legal obstacles to the collection of this information. Firms are free to use any available technology to simplify the gathering of information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection of information is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), on Tuesday, June 30, 1998 in Volume 63, No. 125, page 35601, a 60-day notice for public comment (Attachment D) was published in the Federal Register. FDA received one comment from an association representing hearing aid manufacturers. The comment stated that FDA underestimated the burden for preparing a user instructional brochure as required by 21 CFR 801.420(c). The association stated that their member companies produced at least 18 different models of hearing aids and not the 5 assumed by FDA. The comment further stated that, because some models offer different features, their companies produced, on the average, 24 brochures for their 18 models. Finally, the comment stated that their member companies required not 40 hours but at least 136 hours to produce a User Instructional Brochure.

FDA agrees in part with the comment. FDA agrees that the number of models produced are more than the 5 originally estimated by FDA. FDA notes, however that the estimates proposed by FDA are annual burdens. Not all 18 models and 6 variations cited by the comment are new every year. Therefore, it is not necessary to prepare a new User Instructional Brochure for each of these every year. In addition, much of the information in the brochure can be transferred from one model brochure to the brochure for the successor model.

Based on premarket notification submissions, FDA estimates that approximately half of the models are

significantly revised each year and others may be revised less significantly. FDA accepts the estimate of 136 hours for preparing a new brochure, but believes that an estimate of half that time or 68 hours is more appropriate for preparing a revised brochure.

Industry Contacts

The following groups or individuals contributed comments regarding the burden associated with this information collection (Attachment A):

Audiology Coalition

Coalition commented on Section X, Labeling, and Section III, Response to FDA Question 2. January, 7, 1994.

The coalition suggested changes to new Hearing Aid Rule.

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(On Behalf of the International Hearing Society with support of American Academy of Otolaryngology-Head and Neck Surgery)

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October 9, 1997

Mr. Scheineson commented on the proposed Hearing Aid Rule, and encouraged FDA to share its draft with the regulated community and commence negotiated rulemaking in this matter.

9. Explanation of Any Payment or Gift to Respondents

The regulation does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondent

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA under 21 CFR 801.421 are releasable under 21 CFR Part 20. However, FOIA provides certain exemptions from mandatory public disclosures of government records (5 U.S.C. 522(b)(1-9)). One such provision, 5 U.S.C. 522(b)(4) exempts "trade secrets" and commercial or financial information that is privileged or confidential from the requirement of public disclosure. Labeling information is publicly available. Records maintained by hearing aid dispensers will generally not be in FDA's possession and therefore, not subject to disclosure by FDA. If, however, FDA does obtain records maintained by dispensers, these records will be released under part 20 only.

11. Justification for Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

The estimates below were calculated based on the current hearing aid regulation in Sections 21 CFR 801.421(a)(1) and 21 CFR 801.420(a)(2) and do not reflect changes, if any, anticipated under the FDA's proposed Hearing Aid Rule.

Based on reviews by FDA Inspectors of records of hearing aid dispensers in four FDA districts to determine the level of compliance with existing hearing aid requirements, FDA has developed the following estimates. The estimates relating to 21 CFR Parts 801.421(a)(1) and 801.420(a)(2) in the reporting and recordkeeping burden tables below are based on information obtained by this review. This review revealed that medical evaluations were obtained in 32 percent of the sales and signed waivers were obtained in 60 percent of the sales.

The respondents to this collection of information are expected to be hearing aid manufacturers, distributors (including physicians who are currently dispensing hearing aids), audiologists, dispensers, health professionals, or other for profit organizations.

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

Table 1.--Estimated Annual Reporting Burden

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 (b)	9,900	162	1,600,000	0.30	480,000
801.421 (c)	9,900	5	49,700	0.17	8,449
TOTALS					586,369

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 of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421 (d)	9,900	162	1,600,000	0.25	400,000
Totals:					400,000

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

Explanation of Reporting Burden Estimate:

According to the International Hearing Society, there are about 9,900 hearing aid dispensers in the United States, including 2,200 audiologists in private practice, 2,400 audiologists in clinics of physicians' offices, and 5,300 other hearing aid dispensers. While the vast majority of hearing aids are sold to consumers in person, the sales from and estimated four mail order companies account for about 2 percent of the market. FDA does not have market share data for the remaining sectors, but believes that audiologists and other hearing aid dispensers may account for roughly equal shares of all hearing aid sales.

No costs were calculated for training or purchasing equipment because FDA believes that the mandatory requirements of this regulation are within the current capabilities of hearing aid dispensers.

In statistics compiled by the Hearing Industries Association for the years 1991 through 1993, it was estimated that approximately 1.6 million hearing aids are sold annually in the United States. Since each hearing aid evaluation test must be performed for each individual hearing unit, the cost calculations below are based on the 1.6 million hearing aid units sold annually. This analysis uses \$670 as the average price for a basic hearing aid.

The Unit cost for each required test or procedure was based on the average of the practitioners' submitted charges to Medicare and Medicare's reimbursed rate to providers. Although the Medicare-eligible population purchase about 60 percent of all hearing aids, conversations with Medicare officials suggest that Medicare may cover only some of the diagnostic tests required under the comprehensive hearing assessment provisions, and then only if performed by physicians or audiologists. Moreover, Medicare would be unlikely to cover any of the subsequent evaluation tests. Since less than half of the total testing costs would be

reimbursed by Medicare, the submitted price may better represent the cost to the average consumer. On the other hand, the current Medicare data primarily reflect fees from physicians and audiologists; other hearing aid dispensers may charge less. Therefore, FDA used the midpoint of the two Medicare rates to project its best estimate of an average fee.

FDA estimates that performing these activities would take about 15 minutes for a qualified health care professional. Data based on a submission from the American Speech-Language Hearing Association and a national survey published in the Hearing Instruments Journal, after a 25 percent adjustment for benefits, projects the average annual earnings of Audiologists to be about \$52,500. Similarly, using the same survey and benefits adjustment, the agency estimates the average annual salary for other hearing aid dispensers to be about \$57,500. Assuming audiologists and other hearing aid dispensers each hold roughly equal shares of this market, their average earnings per 15 minute increment comes to approximately \$6.60 per transaction.

For the Sec. 801.421(b) estimate, FDA assumes that 9,900 hearing aid dispensers will have 162 sales annually (1.6 million sales, the current number of annual hearing aid sales, divided by 9,900 dispensers). 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/her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

The 801.421(c) estimate assumes that 40 hearing aid manufacturers/distributors, and 9,900 dispensers will provide copies of the User Instructional Brochure to any health care professional, user, or prospective user who request a copy in writing. It is estimated that 5 written requests for copies of the brochures will be received by each hearing aid manufacturer/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/distributor or hearing aid dispenser locating the appropriate User Instructional Brochure for the specific model and mailing the brochure to the requester.

A reasonable estimate for this industry's wage rate is \$26 per hour. The reporting cost to the respondent is estimated to be \$21,736,494, which is the total hours (836,019) multiplied by \$26.

Explanation of Recordkeeping Burden Estimate:

The 801.421(d) 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. Each recordkeeping entry is estimated to require 0.25 staff hours.

The recordkeeping cost to the respondent is estimated to be \$10,400,000 which is the total recordkeeping hours (400,000) multiplied by \$26.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

Other than the costs listed in item 12 above, there is no other annual cost burden to respondents or recordkeepers.

14. Annualized Cost to the Federal Government

There are no anticipated costs to the Federal Government, since this information need not be submitted to the FDA. Biannual inspections of hearing aid manufacturers, to include reviews of labeling and package inserts, will be conducted under the auspices of the Good Manufacturing Practice (GMP) Regulations, under OMB Clearance (0910-0073).

15. Explanation for Program Changes or Adjustments

There has been no burden change since this information collection's OMB approval on November 26, 1997, when this collection was approved by OMB for a period of one year.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

List of Attachments to Supporting Statement:

- Attachment A - FDA response to OMB, December 5, 1997
- Attachment B - ANPRM, November 10, 1993
- Attachment C - 21 CFR 801.420 and 801.421
Section 520(e) of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 360j(e))
Section 502(q) of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 352(q)) Section
704(a) of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 371(a))
- Attachment D - Federal Register 60 Day Notice soliciting comments on “Hearing Aid Devices: Professional
and Patient Labeling and Conditions for Sale -- 21 CFR Part 801.420 and 801 .421 (OMB
Control Number 0910-0171 -- Extension),” June 30, 1998