

UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device Labeling Regulations

OMB Control No. 0910-0485

RIN 0910-AI21: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

SUPPORTING STATEMENT –

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency or we) rulemaking. In the Federal Register of October 20, 2021 (86 FR 58150), FDA issued a proposed rule “*Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*” (OTC Hearing Aids), proposing to establish a regulatory category and related rules for OTC hearing aids to improve access to hearing aid technology for Americans. The rule also proposes multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category while continuing to provide a reasonable assurance of safety and effectiveness. We believe the proposals set forth in this rulemaking will promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology.

Accordingly, we are requesting OMB approval of the information collection provisions associated with our OTC Hearing Aids proposed rule.

2. Purpose and Use of the Information Collection

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). In addition, stakeholders have cited Federal regulations that require specific labeling and conditions for sale, initially implemented in the late 1970s, as barriers to access. FDA proposes a number of changes to the regulatory framework for hearing aids to remove or reduce barriers to certain air-conduction hearing aids for perceived mild to moderate hearing impairment—the degree of impairment associated with age-related hearing loss—that have the potential to be of great benefit to the public health.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers, packers, and distributors may use any appropriate information technology to develop and distribute the required labeling. While paper copies are often used for labeling accompanying a device, manufacturers may use appropriate information technology to keep records required by the labeling regulations.

Section 502(f) of the FD&C Act authorizes the use of electronic labeling, rather than the traditional paper labeling. Specifically, for prescription devices intended for use in health care facilities or by a health care professional and labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments, respondents may provide labeling for those devices solely in electronic form, so long as the labeling complies with all applicable laws and the manufacturer affords users the opportunity to request the labeling in paper form and promptly provides such labeling to requestors without additional cost.

We estimate that approximately 95% of the respondents use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements. The frequency of the information collection is “occasionally.”

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

There are no special circumstances for this collection of information.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the Federal Register of October 20, 2021 (86 FR 58150). We are currently collecting public comment.

In developing the OTC Hearing Aids proposed rule, FDA held a public workshop on April 21, 2016, entitled “*Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids,*” (announced at 81 FR 784). Comments were requested on several topics related to hearing healthcare technology and improved access, including the appropriate level of GMP regulation (Quality System requirements) to ensure the safety and effectiveness of air-conduction hearing aid devices in consideration of the President’s Council of Advisors on Science and Technology (PCAST) October 2015 report recommendations.

FDA received hundreds of comments to the docket for this workshop prior to the (extended) deadline of June 30, 2016. In addition, 2 keynote speakers (from PCAST and the National Academies of Sciences, Engineering, and Medicine (NASEM)), 12 invited speakers, and 24 public speakers offered comments or presentations at the workshop. Workshop speakers and submitters of docket comments were generally from: healthcare professionals (or healthcare professional organizations), industry, patients or consumers, academics, consensus standards developers, and science organizations.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is associated with the information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although personally identifiable information (PII) is collected, it is collected in the context of the subject individuals’ professional capacity and the FDA-related performed for their employer (e.g., point of contact at a regulated entity). The PII collected is name, email address, telephone number, and address. We determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, neither FDA, nor any contractor uses names or any other personal identifier to routinely retrieve records from the information collected. Through appropriate design, FDA has limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). 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.

Information that is made available in labeling is, by its nature, public information. Information that is trade secret or confidential is subject to FDA’s regulations on the release of information, 21 CFR Part 20.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

We intend the burden estimates to be consistent with our Preliminary Regulatory Impact Analysis (PRIA) for the OTC Hearing Aids proposed rule..

Table 1.--Estimated One-Time Burden^{1,2}

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours	Total Capital Costs (in \$Millions)
Understanding and implementing new regulatory requirements from hearing aids rule	105	1	105	284	29,820	\$4.1
Hearing aids relabeling; one-time burden	105	8	840	68	57,120	\$6
TOTAL			0		0	\$10.1

1 There are no operating and maintenance costs associated with this collection of information.
 2 Numbers have been rounded to the nearest whole number.

Table 2.--Estimated Annual Recordkeeping Burden^{1,2}

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Proposed labeling disclosure records under 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure	105	8	840	1	840

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
 2 Numbers have been rounded to the nearest whole number.

Table 3.--Estimated Annual Third-Party Disclosure Burden^{1,2}

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
OTC Hearing Aid Controls; 800.30	105	7	735	19	13,965
Prescription Hearing Aid Labeling; 801.422	105	1	105	19	1,995
TOTAL					15,960

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
 2 Numbers have been rounded to the nearest whole number.

Our burden estimate is based on FDA Uniform Registration and Listing System data; FDA’s Operational and Administrative System for Import Support data; informal communications with industry; and our knowledge of and experience with information collection

pertaining to medical device labeling. We intend the burden estimates to be consistent with our Preliminary Regulatory Impact Analysis (PRIA) for this rulemaking.

12b. Annualized Cost Burden Estimate

Our estimated annual cost burden for the OTC Hearing Aids proposed rule is based on the labeling cost model used in the PRIA and the wage rates in the U.S. Bureau of Labor and Statistics, [May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 334500 - Navigational, Measuring, Electromedical, and Control Instruments Manufacturing](#) (wage rates have been doubled to account for benefits and overhead):

Occupation code—Occupation name (percentage of burden hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
11-2011—Advertising and Promotion Managers (58%)	9,744	\$144.82	\$1,411,126
27-1024—Graphic Designers (42%)	7,056	\$60.92	\$429,852
Total	16,800		\$1,840,978

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

In the Preliminary Regulatory Impact Analysis for the OTC Hearing Aids proposed rule, estimates a \$10,300,000 one-time cost burden for manufacturers of hearing aids as follows:

Relabeling: The rule will require all current hearing aids to be relabeled according to either the proposed OTC or prescription hearing aid labeling requirements. About 105 firms manufacture air conduction hearing aids of the type that may be affected by the rule. Casual online research indicates one large manufacturer is currently offering 15 models each of which would require new labeling. Smaller manufacturers may offer fewer models. If we estimate the number of products per manufacturer using a uniform distribution running from 1 to 15 with a mean of 8 we get a mean estimate of 840 products requiring relabeling. Based on a compliance date 240 days after publication of a final rule based on this proposed rule (an effective date of 60 days after publication plus a compliance period of 180 days after the effective date), our 2015 labeling cost model suggests a one-time mean cost estimate for relabeling of about \$6 million.

Reading and Understanding the Rule: Using the same labor times and classifications we have used in previous analyses, we assume this may require 5 hours of time for one each of the following three types of personnel: executive, lawyer, and marketing manager. Using recent BLS wage rates we estimate this one-time cost at about \$0.3 million.

Revising Guidelines or Standard Operating Procedures: In addition to the activity required by this rule, manufacturers would need to revise internal guidelines or standard operating procedures (SOPs) to reflect those requirements. Using the same labor times and classifications we have used in previous analyses, we assume this may require up to 25 hours of time for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Using recent BLS wage rates, we estimate this one-time cost at \$4 million.

14. Annualized Cost to the Federal Government

Government costs for implementing the information collection will be absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

We are requesting changes and revisions consistent with our proposed rule. If finalized, we believe there will be an initial burden increase associated with product labeling adjustments and understanding provisions of the new regulations. However, we believe that implementation over time will result in lower burden associated with product labeling for OTC hearing aids, as the regulations are intended to more clearly define these products.

16. Publication and Project Time Schedule

Information collection supports rulemaking included on FDA's Regulatory Agenda.

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.