UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device Labeling Regulations

OMB Control No. 0910-0485 - Revision

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. We are establishing a regulatory category for over-the-counter (OTC) hearing aids to improve access to hearing aid technology for Americans. OTC hearing aids are intended to address perceived mild to moderate hearing loss in people aged 18 or older. Along with the OTC category, we are finalizing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the new OTC category. We have determined that the requirements set forth in the rulemaking will protect the public health by providing reasonable assurance of safety and effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology. This rulemaking also affects other regulations that applied to hearing aids. FDA had established device restrictions for hearing aids that included labeling requirements as well as conditions for sale. We are removing these device restrictions for hearing aids and establishing a new regulation for prescription hearing aid labeling.

We therefore request OMB approval for the information collection provisions established by the final rule, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

3. Use of Improved Information Technology and Burden Reduction

As detailed more fully in Question 12, the burden we attribute to the information collection results from a one-time adjustment to the existing ways in which respondents comply with applicable instruction and requirements (5 CFR 1320.3(b)), and from newly established disclosure requirements and associated recordkeeping. Respondents may use any appropriate information technology to develop and distribute required disclosures (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 95% of respondents will 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

We do not believe the information collection imposes undue burden on small entities. Because the annualized cost over ten years is $0.009 million per firm, which is unlikely to represent more than three percent to five percent of the revenue of an affected manufacturer, FDA has certified that the final rule will not have a significant economic impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements. Labeling is required to market hearing aids. Therefore, the frequency of the information collection is "*occasionally*," as required to receive a benefit.

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 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.11, we published a proposed rule in the Federal Register of October 20, 2021 (86 FR 58150), including an analysis of the proposed information collection, and invited public comment. More than 1,000 comments were received and are discussed in section III of the final rule, "*Comments on the Proposed Rule and FDA's Response*." Comments regarding the information collection are discussed in section "*IX. Paperwork Reduction Act of 1995*," although we have made no adjustment to our burden estimates.

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 considered hundreds of comments from the workshop. In addition, two 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. This ICR does not collect personally identifiable information (PII) or information of a personal nature. The information disclosure is used to inform users and medical professionals regarding the safety and efficacy of the device(s). Recordkeeping is performed to comply with the requirement to maintain the product labeling online for users and medical professionals. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

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.

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

Table 1.--Estimated One-Time Burden

Information Collection 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	290	30,450	$4.1
Hearing aids relabeling; one-time burden	105	8	840	68	57,120	$6
TOTAL			0		87,570	$10.1

Table 2.--Estimated Annual Recordkeeping Burden

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

Table 3.--Estimated Annual Third-Party Disclosure Burden

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

We intend these estimates to be consistent with our Final Regulatory Impact Analysis (FRIA). These figures are 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.

Estimated One-Time Burden: Understanding and implementing new regulatory requirements from hearing aids rule--one-time burden (Recordkeeping): As noted in the FRIA for this rulemaking, we estimate it will take 5 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Also included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Therefore, we estimate a one-time recordkeeping burden of 290 hours for each manufacturer.

Hearing aids relabeling--one-time burden (Third-Party Disclosure): The rulemaking necessitates the relabeling of all current hearing aids (approximately 840). The labeling cost model used in the FRIA suggests, based on a compliance date 240 days after publication of the final rule, a one-time estimated third-party disclosure burden for relabeling of about 68 hours per product.

Estimated Annual Burden: Over-the-Counter Hearing Aid Controls--§ 800.30 (Recordkeeping and Third-Party Disclosure): Section 800.30 sets forth labeling requirements for OTC hearing aids. Section 800.30(c)(1) describes the warnings and other important information that the outside package must bear. Manufacturers must include on the outside package label: certain specified warnings and statements; a weblink to all labeling and any additional resources; contact information to request a paper copy of the labeling; their return policy or absence thereof; if the OTC hearing aid is used or rebuilt, they must declare that fact; the principal display panel must bear the marks "OTC" and "hearing aid"; battery information; and control platform information if applicable.

Section 800.30(c)(2) describes device-specific requirements for labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; other specified information; and any other information necessary for adequate directions for use as defined in § 801.5. Also required under proposed § 800.30(c)(2) is the identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician; the technical specifications required by § 800.30(c)(4); a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid; if applicable, information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation; information regarding repair service or replacements; and, if applicable, a summary of all clinical or non-clinical studies conducted to support the performance of the OTC hearing aid.

Section 800.30(c)(3) provides requirements for the labeling on an OTC hearing aid itself, specifically, serial number, information regarding the battery and, if the OTC hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Section 800.30(c)(5) provides requirements related to software device labeling.

We include no estimate for provisions under proposed § 800.30(c)(1)(i)(A) through (D), (c)(2)(i)(A) through (C), and (c)(2)(iii)(A) through (F) because we consider the labeling to be "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public," consistent with 5 CFR 1320.3(c)(2). Thus, those labeling provisions are not within the definition of collection of information.

The FRIA for this rulemaking estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under §§ 800.30(c)(2) and 801.422(c)(2)).

The rulemaking would necessitate the relabeling of all current hearing aids (approximately 840) according to either the OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the FRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

Prescription Hearing Aid Labeling--§ 801.422 (Third-Party Disclosure): Section 801.422(c) sets forth labeling requirements for prescription hearing aids. However, as with some of the provisions under proposed § 800.30(c), we include no estimate for provisions under § 801.422(c)(1)(i)(A) through (C), (c)(2)(i)(A) through (C), and (c)(2)(ii)(A) through (F) because we consider the labeling to be "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public," consistent with 5 CFR 1320.3(c)(2).

Section 801.422(c)(1) provides the warnings and notice that must be on the outside package labeling; if applicable, that the prescription hearing aid is used or rebuilt; battery information; and if applicable, control platform information.

Section 801.422(c)(2) describes requirements for prescription hearing aid labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; warnings; caution and notices for users; and additional information that must be included in the user instructional brochure.

Section 801.422(c)(3) provides the requirements for the labeling on a prescription hearing aid itself, specifically, serial number; information regarding the battery if applicable; and if the prescription hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Section 801.422(c)(4) provides the technical specification elements that must appear in the user instructional brochure or in separate labeling that accompanies the device.

The FRIA estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under §§ 800.30(c)(2) and 801.422(c)(2)).

The rulemaking would necessitate the relabeling of all current hearing aids (approximately 840) according to either the OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the FRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

12b. Annualized Cost Burden Estimate

Our estimated annual cost burden for the OTC Hearing Aids rule is based on the labeling cost model used in the FRIA and the wage rates in the U.S. Bureau of Labor and Statistics, May 2021 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	$135.50	$1,320,312
27-1024—Graphic Designers (42%)	7,056	$71.24	$502,669
Total	16,800		$1,822,981

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

The Final Regulatory Impact Analysis for the OTC Hearing Aids rule estimates a $10,100,000 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 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 the final 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 rages we estimate this one-time cost at about $0.1 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

Our current estimated cost of $2,633,260 for the information collection pertaining to medical device labeling includes the costs for this rulemaking.

15. Explanation for Program Changes or Adjustments

To reflect one-time burden respondents may incur adjusting to the new requirements, we have added 945 responses and 87,570 hours to our annualized estimate. To reflect recurring burden we attribute to maintaining compliance with the new requirements, we have added 1,680 responses and 16,800 hours annually. Cumulatively, these adjustments result in an increase of 2,625 responses and 104,370 hours annually to the information collection.

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.