UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device Labeling Regulations

OMB Control No. 0910-0485 – Revision

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) implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), codified in Agency regulations and discussed in Agency guidance. Medical device labeling requirements provide for the label or labeling of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices on the labels or labeling for the devices. Section 502(b) of the FD&C Act requires that, for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. Exemptions from labeling requirements may be granted if the agency determines that the adequate directions for use labeling requirements are not necessary in that particular case, as it relates to protection of the public health.

Implementing regulations in parts 800, 801, and 809, and associated regulations in parts 660 and 1040 (21 CFR parts 660, 800, 801, 809 and 1040) set forth content and format requirements manufacturers, importers, and distributors of medical devices must disclose about themselves or the devices, on the label or labeling for the devices to health professionals and consumers.

Provisions found in part 801, subpart B pertaining to labeling requirements for Unique Device Identification are currently approved under OMB control number 0910-0720 and not covered in this information collection request. Information collection associated with labeling requirements for Over-the-Counter (OTC) Devices are found in part 801, subpart C, and cover principal display panel; statement of identity; declaration of net quantity of contents; and certain warning statement elements. Information collection associated with exemptions from adequate directions for use and other exemptions are found in part 801, subparts D and E, respectively. Information collection associated with special labeling requirements applicable to specific devices are found in part 801, subpart H. We also include information collection associated with labeling for in vitro diagnostic products for human use, as set forth in part 809, subpart B.

Section 534 of the FD&C Act (21 U.S.C. 360kk) authorizes the FDA to prescribe performance standards for electronic products to control the emission of electronic product radiation to protect public health and safety. The performance standards may include requirements for warning

signs and labels. Accordingly, FDA promulgated regulations in 21 CFR part 1040, Performance Standards for Light-Emitting Products. Section 1040.20(d) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the specific labeling in addition to labeling required by part 801.

Section 502(u) (21 U.S.C. 352(u)) requires single use devices (SUDs), both new and reprocessed, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Under 502(u), if an original SUD, or an attachment to it, prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If an original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. To assist respondents with information collection associated with these statutory provisions, we developed the guidance document entitled "*Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.*" The guidance document identifies circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act. However, the guidance does not contain additional information collections.

Finally, regulations in 21 CFR parts 660, 801, and 809 now explicitly allow for the use in medical device labeling of stand-alone symbols (not accompanied by explanatory text adjacent to the symbol) established in an SDO-developed standard. The specific regulatory provisions are set forth in 21 CFR part 660, additional standards for diagnostic substances for laboratory standards for biological products, subparts A, C, D, E, and F and in the general medical device labeling regulations part 801, subpart A and part 809, subpart B. Guidance we previously issued in this regard has been withdrawn, however we retain estimates we attribute for respondents who submit symbols glossaries with labeling for medical devices consistent with the applicable regulations. Accordingly, we are requesting OMB approval of the information collection provisions included in the applicable regulations, found in the associated guidance document, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The primary users of the information disclosed on the label or in the labeling for devices are the health professionals who use or prescribe the device or the lay consumers who use the device. The purpose of the information collections is to ensure sufficient information for safe and effective use of medical devices. FDA may also use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use. Failure of the manufacturer, packer, or distributor to label its products in accordance with section 502 of the act may result in the product being misbranded under the act thereby subjecting the firm and the product to regulatory action. Respondents are private sector for-profit businesses.

It is essential to require the specific identification of reprocessed SUDs to ensure that physicians, nurses, users, and hospital administrators know that a device was reprocessed. The intent of the labeling requirement is to ensure that physicians, hospital staff, and patients can identify the reprocessor of a SUD when an adverse event or risk to health information should be attributed to the responsible manufacturer. The information and records generated under this labeling requirement can be used to associate a particular device with a particular manufacturer. This is especially important in the event of a recall, warning, patient injury, or product malfunction.

Section 519 of the FD&C Act requires manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA or the manufacturer. FDA's post-marketing surveillance program cannot work as intended unless health care providers, original manufacturers, device reprocessors, and FDA can readily and accurately identify when a SUD has been reprocessed. The lack of specific labeling to identify reprocessed devices may lead to incomplete and inaccurate reporting of patient injuries and product malfunctions involving reprocessed SUDs, particularly in an instance where a reprocessed device bears only the name or mark of the original manufacturer. The lack of adequate labeling to identify a reprocessor undercuts the purpose and effectiveness of section 519 of the FD&C Act and FDA's medical device reporting regulations such that FDA would lacks accurate information of the postmarket safety and effectiveness of reprocessed SUDs.

Failure of the reprocessor to label the SUD; whether on the device itself, an attachment to the device, or with a detachable label; may result in the product being misbranded under the FD&C Act, subjecting the firm and the product to regulatory action. Any SUD reprocessed from an original device that the original manufacturer has prominently and conspicuously marked must be prominently and conspicuously remarked with the reprocessor's name, a generally recognized abbreviation of its name, or a unique and generally recognized symbol for it.

The information collection will be used by individuals, by the private and public institutions providing healthcare, and by FDA post-market surveillance analysts.

Various symbols with accompanying text have been used in health product labeling for several years, both on package labels and within other labeling documents, such as the instructions for use. The rule continues to allow the use of symbols, including standardized symbols, on device labeling when the symbols are accompanied by explanatory adjacent text.

The likely respondents for this collection of information are domestic and foreign device manufacturers who plan to use stand-alone symbols on the labels and/or labeling of their devices (private sector for-profit businesses and not-for-profit institutions).

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 (as amended) 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 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

Using the guidelines set by the Small Business Administration on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments are considered small businesses.

The requirements in these regulations are the minimum requirements for complying with the provisions of the act. In most cases, the information that is required to be disclosed is information that is available to the firm, including a small business, as a normal course of its doing business.

FDA aids small business and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of Industry and Consumers Education (DICE) within the Center for Devices and Radiological Health. DICE provides workshops, onsite evaluations, and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. DICE also maintains a toll-free 800 telephone number and a website that firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of July 13, 2021 (86 FR 36752). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift has been provided to respondents.

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 in the context of the subject individuals' professional capacity and the FDA-related work 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 have 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 or 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

This information collection does not include any questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Citation	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Part 660, subparts A, C, D, E, and F: Antibody to Hepatitis B Surface Antigen; Blood Grouping Reagent; Reagent Red Blood Cells; Hepatitis B Surface Antigen; Anti-Human Globulin; Part 801 subpart A: General Labeling; Part 809, subpart B: Labeling					
Symbols glossary - 660.2; antibody to Hepatitis B surface antigen requirements, 660.28; blood grouping labeling, 660.35; reagent red blood cell labeling, 660.45, hepatitis B surface antigen labeling, 660.55; anti-human globulin labeling, 801.15; medical devices labeling and use of symbols; 809.10, labeling for in vitro diagnostic products	3,000	1	3,000	1	3,000

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

Our figures are based on data from the FDA Unified Registration and Listing System and the OASIS shipment information. FDA regulations allow for the use of stand-alone graphical representations of information, or symbols, in the labeling for the medical devices and diagnostic substances for laboratory standards, if the symbol has been established in a Standards Development Organization (SDO) developed standard, provided that such symbol is explained in a symbols glossary that is included in the labeling for the medical device and otherwise complies with section 502 (misbranding) of the FD&C Act. These labeling requirements are set forth in 21 CFR part 660, subparts A, C, D, E, and F, in the additional standards for diagnostic substances for laboratory standards for biological products, including: general requirements (21 CFR 660.2), using antibody to Hepatitis B surface antigen (21 CFR 660.28), blood grouping reagent (21 CFR 660.35), reagent red blood cells (21 CFR 660.45), Hepatitis B surface antigen (21 CFR 660.45); and anti-human globulin (21 CFR 660.55). The requirements are also found in the general medical device labeling regulations (part 801, subpart A) and in the in vitro diagnostic product labeling regulations (part 809, subpart B).

Table 2.--Estimated Annual Recordkeeping Burden[1,2]

21 CFR Citation	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Part 801 subpart A: General Labeling Provisions; subpart E: Other Exemptions; subpart H: Special Requirements for Specific Devices					
Processing, labeling, or repacking agreement; 801.150	7,500	887	6,652,500	0.5 (30 minutes)	3,326,250
Impact resistant lenses; invoices, shipping documents, and records of sale or distribution; 801.410(e) and (f)	1,591	47,050	74,856,550	0.0008 (0.048 minutes)	59,885
Hearing aid records; 801.421	10,000	160	1,600,000	0.25 (15 minutes)	400,000

Menstrual tampons, sampling plan for measuring absorbency; 801.430(f)	33	11	363	80	29,040
Latex condoms; justification for the application of testing data to the variation of the tested product; 801.435(g)	51	3.65	186	1	186
Total			83,109,599		3,815,361

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

[2] Numbers have been rounded.

As set forth in § 801.150(a)(2) (21 CFR 801.150(a)(2)), device manufacturers are required to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the final shipment or delivery of the device. Section 801.150(a)(2) requires that copies of this agreement be made available for inspection at any reasonable hour upon request by any officer or employee of the Department of Health and Human Services (HHS). In § 801.410(e) (21 CFR 801.410(e)) copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, are required to be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee acting on behalf of the Secretary of HHS. Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years. Specific recordkeeping requirements applicable to hearing aid dispensers, manufacturers of menstrual tampons, and manufacturers of latex condoms are set forth in 21 CFR 801.421(d), 801.430(f), and 801.435(g), respectively.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1,2]

21 CFR Citation	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Parts 800; and Part 801, subparts A, C, D, and E: General Labeling Provisions; OTC Devices; Exemptions					
Contact lens cleaning solution labeling; 800.10(a)(3) and 800.12(c)	47	8	376	1	376
Liquid ophthalmic preparation labeling; 800.10(b)(2)	25	8	200	1	200
Manufacturer, packer, or distributor information; 801.1	19,407	7	135,849	1	135,849
Adequate directions for use; 801.5	8,526	6	51,156	22.35	1,143,337
Statement of identity; 801.61	8,526	6	51,156	1	51,156
Declaration of net quantity of contents; 801.62	8,526	6	51,156	1	51,156
Prescription device labeling; 801.109	9,681	6	58,086	17.77	1,032,188
Retail exemption for prescription devices; 801.110	30,000	667	20,010,000	0.25	5,002,500

Processing, labeling, or repacking; non-sterile devices; 801.150(e)	453	34	15,402	4	61,608
Part 801, subpart H: Special Requirements for Specific Devices					
Labeling of articles intended for lay use in the repairing and/or refitting of dentures; 801.405(b)(1)	35	1	35	4	140
Dentures; information regarding temporary and emergency use; 801.405(c)	35	1	35	4	140
Hearing aids professional and patient labeling; 801.420	136	12	1,632	80	130,560
Hearing aids, availability of User Instructional Brochure; 801.421	10,000	5	50,000	0.17	8,500
User labeling for menstrual tampons; 801.430	16	8	128	2	256
User labeling for latex condoms; 801.437	52	6	312	100	31,200
Part 809 (in vitro diagnostic products for human use) and Part 1040 (light-emitting products)					
Format and content of labeling for IVDs; 809.10	1,700	6	10,200	80	816,000
Advertising and promotional materials for ASRs; 809.30(d)	300	25	7,500	1	7,500
Labeling of sunlamp products--1040.20(d)	30	1	30	10	300
FD&C Action Section 502(u)					
Establishments listing < 10 SUDs	161	2	322	0.1 (6 minutes)	32
Establishments listing > 10 SUDs	14	45	630	0.1 (6 minutes)	63
Part 660, subparts A, C, D, E, and F: Antibody to Hepatitis B Surface Antigen; Blood Grouping Reagent; Reagent Red Blood Cells; Hepatitis B Surface Antigen; Anti-Human Globulin; Part 801 subpart A: General Labeling Provisions; Part 809, subpart B: Labeling					
Symbols glossary - 660.2; antibody to Hepatitis B surface antigen requirements, 660.28; blood grouping labeling, 660.35; reagent red blood cell labeling, 660.45, hepatitis B surface antigen labeling, 660.55; anti-human globulin labeling, 801.15; medical devices labeling and use of symbols; 809.10, labeling for in vitro diagnostic products	3,000	1	3,000	4	12,000
Total			20,447,205		8,485,061

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

[2] Numbers have been rounded.

Because many labeling provisions correspond to specific recordkeeping requirements, we have accounted for burden attendant to the provisions enumerated in table 3 as third-party disclosures. These figures reflect what we believe to be the average burden incurred by respondents to applicable information collection activities.

12b. Annualized Cost Burden Estimate

We updated the annual cost burden estimate based on the wage rate for a lawyer* ($122), multiplied by the total estimated burden hours (12,303,422).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Attorney	12,303,422	$122	$1,501,017,484

* The estimated wage rate for a lawyer is based on the Bureau of Labor Statistics (BLS) hourly wage rate of $61 (https://www.bls.gov/ooh/legal/lawyers.htm, date accessed September 10, 2021). The hourly wage rate of $122 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

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

There is no capital, start-up, operating or maintenance cost associated with this information collection.

14. Annualized Cost to the Federal Government

Review of labeling occurs generally as part of a premarket notification submissions or premarket approval applications approved under OMB Control Nos. 0910-0120 and 0910-0231. Here we estimate labeling reviews associated with specific requirements. Based on internal data, approximately 10 FTEs are allocated for labeling reviews. Based on FDA/CDRH's cost of $263,326* annually, (which consists of the employee's salary and any overhead which accompanies that employee*), the total estimated annual Federal cost is $2,633,260.

*Based on the FY 2020 FDA Budget Request – Executive Summary – All Table

15. Explanation for Program Changes or Adjustments

This information collection reflects changes and adjustments. For efficiency of operations, we have consolidated related information collections currently approved under OMB control numbers 0910-0577 and 0910-0740. This results in an increase to the information collection of 15,095 burden hours annually. The increase is due to adjustments reflecting updated data and the inclusion of the consolidated information collection. At the same time, we have reduced our

estimate of disclosure responses by 1,597,520 annually. Upon review, we believe we previously double-counted burden ascribed to disclosures provisions having accounted for the same burden as that associated with recordkeeping activities.

Finally, upon submission of the ICR, we are correcting inadvertent calculation errors to the burden hour increase and responses decrease displayed in our 60-day notice. Specifically, additional burden hours have been added to the third-party disclosure burden table to reflect an increase of 12,000 burden hours resulting in a total of 8,485,061 total burden hours for the third-party disclosure burden table. Also, additional responses have been added resulting in a total increase in responses of 21,647,170.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.