4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1048]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0485. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Labeling Regulations

OMB Control No. 0910-0485--Revision

This information collection supports 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 associated Agency guidance. Medical device labeling requirements, among other things, provide for the label or labeling content of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 of the FD&C Act require that manufacturers, importers, and distributors of medical devices disclose information about themselves or the devices on the labels or labeling for the devices. Section 502 provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use. Medical device labeling regulations in parts 800, 801, 809, and associated regulations in parts 660 and 1040 (21 CFR parts 660, 800, 801, 809, and 1040), prescribe the disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves and/or the devices, on the label or labeling for the devices, to health professionals and consumers.

In conjunction with provisions in part 800, part 801, subpart A sets forth general labeling provisions applicable to all medical devices, including content and format requirements pertaining to intended uses, adequate directions for use, misleading statements, and the prominence of required labeling. 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. In addition to the labeling requirements in part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, sunlamp products and ultraviolet lamps are subject to specific labeling requirements as set forth in part 1040.

The information collection also includes provisions associated with stand-alone symbols (not accompanied by explanatory text adjacent to the symbol), when accompanied by a symbols glossary, as set forth in part 660, additional standards for diagnostic substances for laboratory standards for biological products, subparts A, C, D, E, and F. The requirements are also found in the general medical device labeling regulations part 801, subpart A, and part 809, subpart B.

The information collection also helps to implement section 502(b) of the FD&C Act which requires that, for packaged devices, labeling must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires also that the labeling for a device must contain adequate directions for use unless FDA grants an exemption. Section 502(u) requires reprocessed single-use devices (SUDs) 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 this provision, if the 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 the 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. As required by the Medical Device User Fee

Stabilization Act of 2005 (MDUFSA), FDA issued the guidance document, "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" (May 2006), to assist respondents with these requirements. The guidance document was issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website, and this guidance is available at https://www.fda.gov/media/71187/download. The guidance document is intended to identify 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.

In the *Federal Register* of July 13, 2021 (86 FR 36752), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 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 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 (§ 660.2), using antibody to Hepatitis B surface antigen (§ 660.28), blood grouping reagent (§ 660.35), reagent red blood cells (§ 660.45), Hepatitis B surface antigen (§ 660.45); and anti-human globulin (§ 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), 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) 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 §§ 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
Part 800; and Part 801, subparts A, C, D, and E: General Labeling; 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 (22 hours and 21 minutes)	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 (17 hours and 46.2 minutes)	1,032,188
Retail exemption for prescription devices; 801.110	30,000	667	20,010,000	0.25 (15 minutes)	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 (10 minutes)	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.

Overall, the information collection reflects changes and adjustments. For efficiency of operations, we have consolidated related information collection previously approved under OMB control numbers 0910-0577 and 0910-0740. This results in an increase to the information collection by 15,095 burden hours annually (for reporting and disclosure burden related to the symbols glossary regulatory requirements and disclosure burden related to Section 502(u)). We have increased our estimate of the total responses by 21,647,170 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 (by adding 12,000 burden hours to account for disclosure of the symbols glossary) and decrease in total responses displayed in our 60-day notice in the *Federal Register* of July 13, 2021.

Dated: October 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-22043 Filed: 10/7/2021 8:45 am; Publication Date: 10/8/2021]