DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device labeling regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by October 24, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–1048 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Medical Device Labeling Regulations

OMB Control Number 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. In accordance with the Unique Device Identification (UDI) system (see part 801, subpart B (21 CFR part 801, subpart B)), medical device labelers, unless excepted, are required to design and use medical device labels and device packages to bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows.

21 CFR 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under 21 CFR 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

21 CFR 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing agency to furnish FDA an application containing certain information, materials, and supporting documentation.

Under 21 CFR 830.120, an FDA-accredited issuing agency is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

21 CFR 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waive.

21 CFR 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections are required to include UDI data elements for the device that is the subject of such information collection. Addition of the UDI data elements is included in this burden estimate for the conforming amendments in the following 21 CFR parts: part 803—Medical Device Reporting (OMB control number 0910–0437), part 806—Medical Devices; Reports of Corrections and Removals (OMB control number 0910–0359), part 814—Premarket Approval of Medical Devices (OMB control number 0910–0231), part 820—Quality System Regulation (OMB control number 0910–0073), part 821—Medical Device Tracking Requirements (OMB control number 0910–0442), and part 822—Postmarket Surveillance (OMB control number 0910–0449).

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 of the FD&C Act 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. 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) of the FD&C Act 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, 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/regulatory-information/search-fda-guidance-documents.*

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR citation	Number of respondents	Number 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
UDI; part 801, subpart B	[2] 6,199	51	[3] 316,149	0.0167 (1 minute)	5,280
Total					8,280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
[3] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

Our figures are based on data from the FDA Unified Registration and Listing System and the Operational and Administration System for Import Support 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	Number of recordkeepers	Number 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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]—Continued

21 CFR citation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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
UDI; part 801, subpart B	[3] 5,987	51	[4] 305,337	0.9833 (59 minutes)	300,238
Total			83,414,936		4,115,599

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.
[3] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
[4] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

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	Number of respondents	Number 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	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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]—Continued

21 CFR citation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
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
Part 801, subpart B					
UDI	[3] 5,987	51	[4] 305,337	0.8833 (53 minutes) ..	269,704
Total	.....	.....	20,752,542	.....	8,754,765

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.
[3] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.
[4] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

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.

We are revising this information collection to include OMB control number 0910–0720. Our estimated burden for the information collection reflects an overall increase of 579,633 hours and a corresponding increase of 926,823 responses/records. We attribute this adjustment to the revision of this information collection to include OMB control number 0910–0720.

Dated: August 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18275 Filed 8–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4951]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

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 September 23, 2022.

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 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.