Dated: March 13, 2019.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2019–05115 Filed 3–18–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0549]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Use of Symbols in Labeling—Glossary to Support the Use of Symbols in Labeling

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 product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as ''stand-alone symbols'') if certain requirements are met.

DATES: Submit either electronic or written comments on the collection of information by May 20, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2019–N–0549 for ''Use of Symbols in Labeling.'' 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.

- 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.gpo.gov/fdsys/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.

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. 3501–3520), 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 Devices: Use of Symbols in Labeling—Glossary To Support the Use of Symbols in Labeling

OMB Control Number 0910–0740—Extension

In the **Federal Register** of June 15, 2016 (81 FR 38911), FDA issued a final rule revising medical device and certain biological product labeling regulations by explicitly allowing for the optional use in medical device labeling of stand-alone symbols established in a Standard Development Organization (SDO)-developed standard. In particular, FDA will allow the use of stand-alone graphical representations of information, or symbols, in the labeling for the medical devices, if the symbols are established in a standard developed by an SDO as long as: (1) The standard is recognized by FDA under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(c)) and the symbol is used according to the specifications for use of the symbol set forth in FDA's section 514(c) recognition, or alternatively, (2) if the symbol is not included in a standard recognized by FDA under section 514(c) of the FD&C Act or the symbol is in a standard recognized by FDA but is not used according to the specifications for use of the symbol set out in the FDA section 514(c) recognition, the device manufacturer otherwise determines that the symbol is likely to be read and understood by the ordinary individual under customary conditions of purchase and use and uses the symbol according to the specifications for use of the symbol set forth in the SDO-developed standard. In addition, in either case, the symbol must be explained in a written or electronic symbols glossary that is included in the labeling for the medical device. Furthermore, the labeling on or within the package containing the device must bear a prominent and conspicuous statement identifying the location of the glossary that is written in English or, in the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be used. The use of such symbols must also comply with other applicable labeling requirements of the FD&C Act, such as section 502(a) and (f) (21 U.S.C. 352(a) and (f)).

The 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 for their devices marketed in the United States.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Glossary	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.

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

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per response	Total hours
Glossary	3,000	1	3,000	4	12,000

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

The estimated burden is based on the data in a similar collection for recommended glossary and educational outreach approved under OMB control number 0910–0553 (''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use''). As such, the PRA also covers the requirements of the final rule to submit the symbols glossary to FDA in otherwise required submissions during the premarket review process and to disclose it to third parties in otherwise required device labeling, which means adding to such submission or labeling a compiled listing of each SDO-established symbol used in the labeling for the device; the title and designation number of the SDO-developed standard containing the symbol; and the title of the symbol and its reference number, if any, in the standard; and the meaning or explanatory text for the symbol as provided in the FDA recognition or, if FDA has not recognized the standard or portion of the standard in which the symbol is located or the symbol is used not in accordance with the specifications for use of the symbol set out in the FDA section 514(c) recognition, the explanatory text as provided in the standard.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 14, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–05133 Filed 3–18–19; 8:45 am]

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