4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0549]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 (PRA).

DATES: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0740. 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.

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.

In the *Federal Register* of March 19, 2019 (84 FR 10100), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received the following comments:

- Comment supporting the use of the existing rule to continue the use of symbols without explanatory text, and including additional instructions, as needed, in the symbols glossary.
- Comment suggesting the development or use of the symbol for electronic instructions for use be included.
- Comment suggesting adding requirements regarding education on the meaning of symbols in devices.
- Comment requesting future support on the use of "homegrown" or proprietary symbols not contained in a standard from a recognized SDO to reduce burden on space limited areas.
- Several comments requesting that we not mandate the inclusion of the title and designation number in the glossary because the commenters believe they are not necessary for

the user of the medical device to understand the symbol. The commenters assert that removing the requirement for title and designation number may permit more symbols glossaries to be included in a paper Instructions for Use (IFU) versus needing to be on a website due to the amount of information needed. The commenters assert this is beneficial in that it may permit more users to see the glossary more easily than going to a web-based glossary. The comments also assert that information such as the title and designation number could be part of the submission content, rather than part of the labeling/IFU.

- Comment suggesting the use of the International Standards Organization (ISO) Symbol 1641 (Consult IFU) to replace the requirement to bear a prominent and conspicuous statement identifying the location of the symbols glossary. The comment asserts that use of ISO Symbol 1641 is believed to be globally well understood to indicate any information needed to understand the proper use of the device is in the IFU. Use of ISO symbol 1641 will also reduce burden and costs as the statement in English requires translation for use in other countries, whereas the symbol is universal.

FDA has reviewed and continues to consider comments to the extent that they relate to this information collection. We note that we continuously evaluate ways to improve stakeholder understanding of the symbols rule. We have made no changes to the information collection at this time as a result of the comments. Based upon comments received, FDA also notes that existing symbols contained within standards for an electronic IFU exist, which are intended to indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.

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

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

Activity	No. of Respondents	No. 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	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	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: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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