U.S. Food and Drug Administration
Medical Devices: Use of Symbols in Labeling--Glossary to Support the Use of Symbols in Labeling

0910-0740
RIN 0910-AG74

SUPPORTING STATEMENT

Terms of Clearance: n/a

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 502 of the FD&C Act (21 U.S.C. 352) requires that industry provide clear and understandable labeling for FDA-regulated products. A device is deemed misbranded, among other reasons, if its labeling is false or misleading (section 502(a)), if the required information on the labeling fails to appear in terms that are "likely to be read and understood by the ordinary individual under customary conditions of purchase and use" (section 502(c)), or if its labeling does not bear "adequate directions for use" (section 502(f) of the FD&C Act). Section 502 further provides that a device is misbranded if the required labeling is not "prominently placed" and "conspicuous" as compared with other words, statements, and other information in the labeling.

FDA has further defined labeling requirements for devices by regulation, requiring, in part 801 (21 CFR part 801), that "[a]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language…" (§ 801.15(c)(1)). The regulation goes on to allow for use of foreign language under certain circumstances. Under the previous regulation, graphics, pictures, or symbols in labeling that represent required information must be accompanied by explanatory English text adjacent to the symbol in order to "appear thereon in the English language."

In the Federal Register of June 15, 2016 (81 FR 38911), FDA issued a final rule revising parts 660, 801, and 809 to 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.

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 symbol has been established in an 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.

FDA is also revising its prescription device labeling regulations to authorize the use of the symbol statement "Rx only" in the labeling for prescription devices. However, this not a "collection of information" because it is information originally supplied by the Federal government for the purpose of disclosure to the public (see 5 CFR 1320.3(c)(2)).

2. Purpose and Use of the Information Collection

The medical device industry has requested permission to use stand-alone symbols in device labeling in order to make the label more user-friendly by replacing small, difficult-to-read text with pictorial information and to harmonize the labeling requirements of U.S. and foreign regulatory bodies.

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

This labeling information is reported using paper and electronic means during the product application process for FDA review/approval (under OMB control numbers 0910-0120, 0910-0231, 0910-0078, 0910-0844, 0910-0332, 0910-0485, and 0910-0338).

The symbols glossary in this ICR may be provided in either paper or electronic format. We expect that the information will be disclosed electronically approximately 95% of the time.

4. Efforts to Identify Duplication and Use of Similar Information

Under the final rule revising parts 660, 801, and 809, FDA seeks to harmonize U.S. regulatory requirements with those of the European Commission by allowing stand-alone symbols to be used in medical device labeling if the symbol has been established in an SDO-developed standard, provided that such symbol is explained in a symbols glossary that is included in the labeling for the medical device. As such, choosing to use stand-alone symbols under the rule would potentially reduce the burden associated with designing and re-designing the labels on medical devices that are currently marketed in the United States and the European Union.

5. Impact on Small Businesses or Other Small Entities

This collection will not have a significant impact on small businesses. The use of stand-alone symbols in device labeling is optional under the final rule. Those device manufacturers who now use labels without symbols, or who use symbols with adjacent explanatory text, may continue to do so. Therefore, medical device manufacturers would

use stand-alone symbols as allowed by the final rule only if they expect a positive net benefit.

6. Consequences of Collecting the Information Less Frequently

The regulations generally require that labeling accompany each shipment of a device. If this were not done, the device user may not have the necessary information for the safe and effective use of the device. Therefore, the collection occurs "occasionally."

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 March 19, 2019 (84 FR 10100). FDA received the following comments:

- Comment supports 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 standard developing organization (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 comment believes they are not necessary for the user of the medical device to understand the symbol . The comment believes that removing the requirement for title & designation number may permit more symbols glossaries to be included in a paper IFU vs needing to be on a website due to the amount of information needed. The comment believes this is beneficial in that it may permit more users to see the glossary more easily than going to a web-based glossary. The comment also asserts 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 ISO Symbol 1641[Consult Instructions for Use (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 each comment. We are evaluating ways to improve stakeholder understanding of the symbols rule and the available options for using symbols in device labeling. Based upon comments received, FDA does note 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.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration related to the submission or disclosure of symbols.

10. Assurance of Confidentiality Provided to Respondents

This information collection request (ICR) is not collecting personally identifiable information (PII) or other data of a personal nature. Industry is required to provide clear and understandable labeling for FDA-regulated products. This ICR is for label and symbol requirements. Label and package inserts are included in premarket submissions. Labels are required to have the name and address of the manufacturer and/or distributor.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined that personally identifiable information (PII) is not collected and the Privacy Act of 1974 does not apply.

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.

Confidentiality of data and disclosure regarding the existence of an application to the FDA is governed by 21 CFR 814.9, the Freedom of Information Act (FOIA) (5 U.S.C. 552), and sections 301(j) and 520(c) and (h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331(j), 360(c) and (h)). Under FOIA, 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). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4). Part 20 of FDA's regulations, 21 CFR Part 20, sets forth FDA's general policy concerning public availability of FDA records.

11. Justification for Sensitive Questions

The 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

12 a. Annualized Hour Burden Estimate

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

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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours 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.--Third Party Disclosure Burden[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours 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 approved under OMB control number 0910-0553 (Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use).

12b. Annualized Cost Burden Estimate

There is no annualized cost burden associated with this collection. In fact, our analysis suggests that companies could reap moderate cost savings via switching to using symbols. On average, companies who switch to using symbols could expect to receive an average annual cost savings ranging from $1,000 to $4,000 per UPC. As a result, it is possible that providing medical device manufacturers with the option to use symbols may encourage companies, including small entities, to either start exporting products or export more products.

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

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

14. Annualized Cost to the Federal Government

This collection is part of the normal operating procedures of CDRH and thus there are no additional costs associated with this activity.

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with Section 533 of the Act.

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.