Medical Devices: Use of Certain Symbols in Labeling--Glossary to Support the Use of Symbols in Labeling

0910- NEW

ABSTRACT:

FDA is proposing to revise medical device and biological product labeling regulations to explicitly allow for the use in medical device labeling of certain stand-alone symbols contained in a standard that FDA recognizes under its authority under section 514(c) of the FD&C Act.

In particular, FDA will allow the inclusion of certain stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a standard developed by a nationally or internationally recognized SDO and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices, provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device.

As such the requirement to submit to FDA and disclose to third-parties a symbols glossary, which means "a compiled listing of (i) each symbol used in the labeling of the device, and (ii) the meaning of or explanatory text for the symbol," is subject to the PRA.

Medical Devices: Use of Certain Symbols in Labeling--Glossary to Support the Use of Symbols in Labeling Insert Title of Information Collection

0910-NEW
RIN 0910-AG74

PROPOSED RULE 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).

   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, but does not mention the use of graphics, pictures, or symbols to communicate information. Under the current 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."

   FDA is proposing to revise parts 660, 801, and 809 to expressly allow for the use in medical device labeling of certain "stand-alone" symbols (not accompanied by explanatory text adjacent to the symbol) contained in a standard that FDA recognizes under its authority under section 514(c) of the FD&C Act, as long as a "symbols glossary" contemporaneously accompanies the device.

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 proposed rule will continue to allow the use of symbols, including standardized symbols, on device labeling when the symbols are accompanied by explanatory adjacent text.

The respondent community could represent Individuals or households and Private Sector (business or other for-profit, not-for-profit institution).

3. Use of Improved Information Technology and Burden Reduction

This ICR is a reporting during the application process for FDA review and a third-party disclosure requirement related to FDA approved labeling. As such this ICR does not lend itself to the use of improved information technology.

The information is already collected electronically 95% of the time, by the FDA, as part of the currently approved application process.

4. Efforts to Identify Duplication and Use of Similar Information

Under our proposed 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 standardized symbols recognized by FDA to be used in medical device labeling when a symbols glossary contemporaneously accompanies the medical device. as a result this effort should reduce the burden associated with labeling development.

5. Impact on Small Businesses or Other Small Entities

This collection will not have a significant impact on small businesses. Choosing to adopt the rule would potentially reduce the costs to manufactures, as it relates to the designing and re-designing the labels on medical devices that are currently sold in the United States and the European Union.

6. Consequences of Collecting the Information Less Frequently

Because a requirement relates to a specific device and specific situation, it would be most accurate to say that this is a one time collection.

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

FDA published a Proposed Rule (78 FR 23508 in the FEDERAL REGISTER on 04/19/2013

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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 required in an application or disclosure of symbols does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: 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. 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 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).

In addition to the proposed third-party disclosure requirements referenced previously, this proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910-0231; the collections of information under part 801 and § 809.10 have been approved under OMB control number 0910-0485; and the collections of information in §§ 660.2, 660.28, 660.35, 660.45, and 660.55 have been approved under OMB control number 0910-0338.

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 costs 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 costs associated with this activity.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of the OMB

Form 83-I.