POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained in paper and/or electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are retrieved by the name or other programmatic identifier assigned to the individual about whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with the National Archives and Records Administration General Records Schedule 2.8 Employee Ethics Records, these records are generally retained for a period of six years after filing, or for such other period of time as is provided for in that schedule for certain specified types of ethics records. In cases where records are filed by, or with respect to, a nominee for an appointment requiring confirmation by the Senate when the nominee is not appointed and Presidential and Vice-Presidential candidates who are not elected, the records are generally destroyed one year after the date the individual ceased being under Senate consideration for appointment or is no longer a candidate for office. However, if any records are needed in an ongoing investigation, they will be retained until no longer needed in the investigation. Destruction is by shredding or electronic deletion.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

These records are maintained in file cabinets which may be locked or in specified areas to which only authorized personnel have access. Access to the data in the executive branch-wide *Integrity* public financial disclosure information system and OGE electronic systems is protected by electronic controls, such as multifactor authentication and password protection. Access to the systems is controlled based on user roles and responsibilities. Executive branch agencies control their users' access to information in *Integrity* and are responsible for properly safeguarding the records maintained in their systems.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should contact the appropriate office as shown in the Notification Procedure section. Individuals must furnish the following information for their records to be located and identified:

a. Full name.

b. Department or agency and component with which employed or proposed to be employed.

c. Dates of employment.

d. A reasonably specific description of the record content being sought.

Individuals requesting access to records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606).

CONTESTING RECORD PROCEDURES:

Because the information in these records is updated on a periodic basis, most record corrections can be handled through established administrative procedures for updating the records. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the appropriate office shown in the Notification Procedure section.

NOTIFICATION PROCEDURES:

Individuals wishing to inquire whether this system of records contains information about them should contact, as appropriate:

a. For records filed directly with OGE by non-OGE employees, contact the General Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917;

b. For records filed with a Designated Agency Ethics Official (DAEO) or the head of a department or agency, contact the DAEO at the department or agency concerned; and

c. For records filed with the FEC by candidates for President or Vice President, contact the FEC General Counsel, Federal Election Commission, 999 E Street NW, Washington, DC 20463.

Individuals wishing to make such an inquiry must furnish the following information for their records to be located and identified:

a. Full name.

b. Department or agency and component with which employed or proposed to be employed.

c. Dates of employment.

Individuals seeking to determine if an OGE system of records contains information about them must also follow OGE's Privacy Act regulations regarding verification of identity (5 CFR part 2606).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This system of records was originally published in full at 55 FR 6327 (Feb. 22, 1990) and subsequently amended by the following notices: 68 FR 3097 (Jan. 22, 2003); 68 FR 24744 (May 8, 2003); 76 FR 24489 (May 2, 2011); 77 FR 45353 (July 31, 2012); 78 FR 73863 (Dec. 9, 2013).

Approved: September 4, 2019.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2019–19372 Filed 9–6–19; 8:45 am]

BILLING CODE 6345–03–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 October 9, 2019.

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	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 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.

[FR Doc. 2019–19351 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3840]

Electronic Submissions; Data Standards; Support for Unified Code for Units of Measure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its adoption of the most current set of the Unified Code for Units of Measure (UCUM) codes. The UCUM is a terminology standard that contains a system of coding units of measure used in science and medicine. UCUM offers a single coding system for units of measure that does not contain ambiguities amongst electronic communication, and assigns a concise semantics to each defined unit. FDA is encouraging sponsors and applicants to use UCUM standard for drug establishment registration and drug listing, as well as for content of product labeling provided in regulatory submissions to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

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–3840 for ''Electronic Submissions; Data Standards; Support for Unified Code for Units of Measure.'' Received comments 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 laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://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: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *cderdatastandards@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: On May 23, 2005, the Secretary of the