TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application	600	1	600	1.33	798

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

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30967 Filed 12–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Unique Device Identification System

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.

DATES: Fax written comments on the collection of information by January 23, 2017.

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 0910–0720. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Unique Device Identification System OMB Control Number 0910–0720—Extension

In accordance with the collection of information entitled ''Unique Device Identification System (UDI),'' medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

The recordkeeping, reporting, and third-party disclosure requirements referenced in this document are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers include a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. Respondents may also include any private organization that applies for accreditation by FDA as an issuing agency.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows:

Section 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing agency to furnish FDA an application containing certain information, materials, and supporting documentation.

Under § 830.120, an FDA-accredited issuing agency is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs, and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver.

Section 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections (listed below) are required to include UDI data elements for the device that is the subject of such information

collection. Addition of the UDI data elements is included in this burden estimate for the conforming amendments in the following 21 CFR parts:

- Part 803—Medical Device Reporting (OMB control number 0910–0437).
- Part 806—Medical Devices; Reports of Corrections and Removals (OMB control number 0910–0359).
- Part 814—Premarket Approval of Medical Devices (OMB control number 0910–0231).
- Part 820—Quality System Regulation (OMB control number 0910–0073).
- Part 821—Medical Device Tracking Requirements (OMB control number 0910–0442).
- Part 822—Postmarket Surveillance (OMB control number 0910–0449).

In the **Federal Register** of September 16, 2016 (81 FR 63768), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice, containing multiple comments.

(Comment 1) The commenter questioned the practical utility of certain data elements (''Kit'' and ''Unit of Use DI number'') in the GUDID and stated that they do not consider them necessary for the proper performance of FDA's functions.

(Response 1) Kit is an optional data element in the GUDID. The respondent may choose not to provide this information. Certain kits may include individual devices that may not be required to have a UDI. It is therefore useful to be able to identify whether a device reported in GUDID is an individual device or a kit. The Unit of Use data element is used when the base package contains multiple units of the same device. Although not included on the device label, the Unit of Use DI number can specifically identify device use on the patient by either pulling it from AccessGUDID or hospital systems and linking/populating the information to the patient electronic health record. The UDI stakeholder community, which includes clinicians, healthcare providers and labelers, have expressed to us that this is a valuable data element to be in included in GUDID.

(Comment 2) The commenter expressed concern that capital or operating and maintenance costs were excluded from the PRA burden analysis.

(Response 2) While we did include an estimate of costs in the economic analysis of the final rule, this information was not in the PRA section of the final rule or subsequently, the 60-day notice for comment on the extension of this information collection. We appreciate the comment and have included estimated costs of $85.7 million, based on the economic analysis of the final rule, in our analysis of the information collection burden. The estimate includes planning and administration and the costs to integrate the UDI into existing information systems; to install, test, and validate barcode printing software; and to train employees. Other significant components of one-time costs include costs to redesign labels of devices to incorporate the barcode and date format, and to purchase and install equipment needed to print and verify the UDI on labels. In addition, labelers will incur one-time costs for recordkeeping and reporting requirements, and the direct marking of certain devices. The largest annual cost components include labor, operating, and maintenance associated with equipment for printing operations, and labor related to software maintenance and training needed to maintain the UDI information system. The total cost, which includes both capital costs and operating and maintenance costs, has been annualized over 10 years. We have included the total under capital costs for purposes of this information collection request.

(Comment 3) The commenter suggested the following opportunities for FDA to enhance data quality, utility, and clarity of the information, including for FDA to:

- Provide data structure information for relevant conforming amendments;
- clarify how to address challenges of device systems;
- make more timely updates to related FDA databases and enhance interaction between systems; and
- increase GUDID performance to be more consistent and predictable.

Additionally, the commenter suggested additional ways that FDA could minimize the burden of collection of information if FDA were to identify PMA supplement numbers through the PMA database, rather than having the data provided again through GUDID by the labeler.

- More timely updates of Global Medical Device Nomenclature codes.
- Added transparency regarding logic and validation rule changes.
- Auto-populating data elements which already reside in another FDA system.

(Response 3) These comments continue to be evaluated, but FDA is making no change to the information collection at this time.

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

TABLE 1—ESTIMATED ANNUAL BURDEN

	Number of respondents [1]	Number of responses per respondent [2]	Total annual responses [3]	Average burden per response (in hours) [4]	Total hours [5]	Total operating and maintenance costs
Reporting	6,199	51	316,149	0.023 (1 minute)	7,289	$425,000
Recordkeeping	5,987	51	305,337	0.989 (59 minutes)	302,121	14,733,333
Third-Party Disclosure	5,987	51	305,337	0.885 (53 minutes)	270,143	13,033,333

[1] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[2] Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[3] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[4] Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in parentheses.

[5] Total Hours is based on a more precise Burden per Response than the rounded value shown in this table.

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30966 Filed 12–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 046

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 046'' (Recognition List Number: 046), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective December 23, 2016.

ADDRESSES: You may submit comments 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 046.'' 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 046.

- 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 046 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 046 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 046'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287, *standards@cdrh.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device