4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1048]

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

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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0485. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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 Device Labeling Requirements; Unique Device Identification

OMB Control Number 0910-0485--Revision

This information collection supports implementation of section 519(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(f)), requiring the establishment of a unique device identification (UDI) system by FDA. Medical device labeling requirements governed by section 502 of the FD&C Act (21 U.S.C. 352) provide that every medical device and every device package bear a unique device identifier. Implementing regulations are found in part 801, subpart B (21 CFR part 801, subpart B) (Labeling Requirements for UDI), including provisions for exceptions from UDI requirements (21 CFR 801.30). Applicable regulations are also found in part 821 (21 CFR part 821) (Medical Device Tracking Requirements); 21 CFR part 822 (Postmarket Surveillance); part 814 (21 CFR part 814) (Premarket Approval of Medical Devices); and part 820 (21 CFR part 820) (Quality System Regulations), as well as regulations pertaining to in vitro device labeling, biological device product labeling, or any article subject to the device labeling provisions in section 502 of the FD&C Act. Products not in compliance with requirements set forth in the applicable statutory and regulatory authorities may be subject to enforcement action by FDA.

For operational efficiency, we are revising the information collection to include burden that may be attributable to activities associated with provisions found in part 830 (21 CFR part 830), currently approved in OMB control number 0910-0720 and established through rulemaking on September 24, 2013 (0910-AG31). The regulations define relevant terms, identify specific data requirements, and incorporate global standards applicable to the use and discontinuation of a UDI. The regulations also provide for FDA accreditation of an issuing agency (21 CFR 830.110) and explain associated information collection activities including the establishment, maintenance, and disclosure of records. Finally, the regulations provide for administration of the Global UDI Database (GUDID) (part 830, subpart E), which specifies data that must be submitted to FDA to be made publicly available. Users of the GUDID will be able to use the

device identifier portion of the UDI to query descriptive data about a specific device. The GUDID may be accessed on our website at https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid.

In the *Federal Register* of August 24, 2022 (87 FR 51989), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received. However, upon further review and evaluation, we have made adjustments to our estimated burden for the collection of information, as follows:

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

Part 801, subpart B: Labeling Requirements for Unique Device Identification	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Requirements for a unique device identifier under part 830	6,199	51	316,149	1	316,149

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

Our figures are based on economic analysis from previous Agency rulemaking. We assume most burden associated with activities applicable to satisfying UDI requirements as prescribed by part 830 is accounted for in currently approved information collections. For example, information collection associated with medical device tracking provisions in part 821 is currently approved in OMB control number 0910-0442; information collection associated with premarket approval of medical devices (part 814) is currently approved in OMB control number 0910-0231. Similarly, information collection associated with our quality system regulation (part 820) and information collection associated with our medical device recall authority (21 CFR part 810) is approved in OMB control numbers 0910-0073 and 0910-0432, respectively. We assume burden respondents may have incurred as the result of any product relabeling, as well as one-time burden that respondents may have incurred resulting from integrating requirements into current tracking and labeling activities, has since been realized and is now accounted for among our currently approved inventory. Here, we are accounting for burden associated with UDI requirements prescribed by part 830 not otherwise included in currently approved collections and subject to general medical device labeling requirements established in part 801, subpart B.

Because the PRA defines a recordkeeping requirement to include retained records, third-party notifications and disclosures, and reporting to the Federal government as well as the public, we have accounted for these activities cumulatively, characterizing them as recordkeeping activities.

Dated: February 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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