assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910–0769—Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to CDRH. An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (*https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form*), by email, or by regular mail.

Allegations of regulatory misconduct related to medical devices and electronic products are reviewed by CDRH. CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients. There are different processes based on the type of allegation and the completeness of the information submitted. The general steps CDRH takes after receiving an allegation of regulatory misconduct and some examples of the kind of allegations FDA has received are provided on our website (*https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct*).

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
Electronic submission of voluntary allegations to CDRH	2,500	1	2,500	0.25 (15 minutes)	625

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

We recently consolidated the intake of allegations across CDRH Offices. This has improved our estimate and we have adjusted the number of responses accordingly. The number of responses is based on the voluntary allegations received by CDRH in 2022. The adjusted estimated burden for the information collection reflects an increase of 900 responses and a corresponding increase of 225 hours.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12488 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0084]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 July 12, 2023.

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 0910–0471. 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.

Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))

OMB Control Number 0910–0471—Extension

Section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act (21 U.S.C. 360i(b)(5)(A)). This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called MedSun. FDA is seeking OMB clearance to continue to use electronic data collection to obtain information related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions, which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and includes approximately 300 facilities. In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same website as the report information. The burden estimate is based on the number of facilities participating in MedSun (300). FDA estimates an average of 18 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

In the **Federal Register** of January 19, 2023 (88 FR 3417), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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
Adverse event reporting	300	18	5,400	0.5 (30 minutes)	2,700

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

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: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12483 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1889]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by July 12, 2023.

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 0910–0120. 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.

Premarket Notification of Devices

OMB Control Number 0910–0120—Revision

This information collection helps support implementation of statutory provisions that govern premarket clearance of devices. Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), establish premarket notification procedures. Persons who intend to market a medical device, for which a premarket approval application (PMA) is not required, must submit a premarket notification to FDA, unless the device is exempt from 510(k) requirements and does not exceed the limitations of exemptions of the device classification regulations, at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially