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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-7129]

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

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 0910-0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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 July 17, 2026 (91 FR 44863), FDA published a 60-day notice soliciting public comment on the proposed extension of OMB Control Number 0910-0471. FDA received one comment, submitted by an individual quality engineer with professional experience in medical device manufacturing, adverse event investigation, and CAPA program management. The commenter expressed support for the extension of the MedSun collection and offered suggestions in response to each of the four questions posed in the notice.

With respect to cost and hour burden, the commenter questioned the accuracy of the 30-minute-per-response estimate, noting that complex reports — particularly those involving serious injury, death, or multiple interacting devices — likely require significantly more time, especially in the specialty clinical environments FDA is actively recruiting (e.g., pediatric ICUs, electrophysiology labs). The commenter recommended that FDA validate the estimate against a stratified sample of actual reports broken out by complexity level, and that supplemental follow-up questions be counted as a separate burden line item, as they involve additional staff time not captured in the initial submission estimate.

The current estimate of 0.5 hours per response reflects the average burden across all report types based on historical data and network feedback, and FDA considers it a reasonable approximation for PRA purposes. FDA will consider stratified burden estimation in the next renewal cycle.

The commenter also suggested several data quality and efficiency improvements — including adoption of IMDRF adverse event codes, UDI prompting with auto-population, a tiered short/long form structure, EHR integration via FHIR-based exchange, and the provision of aggregate feedback to participating sites. While these suggestions are outside the scope of the

current PRA clearance, FDA will consider them in the context of ongoing MedSun program development and future collection instrument updates.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Adverse Event Reporting	300	18	5,400	.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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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