



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) 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 **[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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 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, 10A63, 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

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the 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. 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 the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910-0291) 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 250 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 Web site as the report information.

The burden estimate is based on the number of facilities participating in MedSun (250). FDA estimates an average of 15 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, 2017 (82 FR 6566), 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 Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Adverse event reporting	250	15	3,750	.75 (45 minutes)	2,813

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

Dated: May 22, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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