

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0017]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Pilot Program for Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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 Pilot Program for Medical Devices—(OMB Control Number 0910–0471—Extension)**

FDA is requesting approval from OMB for clearance to continue to conduct a pilot project to evaluate aspects of a national reporting system mandated by the Food and Drug Modernization Act (FDAMA) of 1997. Under section 519(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(b)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions; user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of FDAMA amended section 519(b) of the act. This amendment legislated the replacement of a 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 act.

FDA is the regulatory agency responsible for the safety and effectiveness of medical products including medical devices and radiological products. Important questions about medical devices, such as those concerning user experience, durability, and rare effects may not be answered until after the device has been marketed. To protect the public health, FDA must be able to rapidly collect information pertaining to adverse events associated with medical devices after they have been marketed. This system is called the Medical Product Surveillance Network (MedSun). The current universal

reporting system remains in place during the pilot stages of the new program, and until FDA implements the new national system by regulation. 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.

Before writing a regulation to implement the large-scale national MedSun reporting system, FDA has been conducting a pilot project to ensure all aspects of the new system address the needs of both the reporting facilities and FDA. This pilot project began with a small sample (approximately 25) and was planned to increase to a larger sample of approximately 250 facilities over a period of approximately 3 years. Data collection began in February 2002 and has been increasing since that time. FDA has achieved its recruitment goals each year, reaching 180 sites at the end of fiscal year (FY) 2003. FDA will reach a total of 240 for FY 2004 and will reach the final goal of 250 by FY 2005. The program has proven to be very popular with sites as FDA has gained a national reputation, with hospitals waiting in line to join.

However, FDA's current resources will not permit FDA to expand beyond 250 sites at this time.

The pilot originally had the following three parts to the data collection: (1) Collecting demographic profile information about the participation facilities, (2) implementing an electronic version of the portions of the MedWatch form (FDA Form No. 3500A, OMB control number 0910-0291) used to report adverse events occurring with medical devices, and (3) adding additional voluntary questions to the data collection. To date, these three features remain unchanged. However, there has been an addition to the data collection that was approved by OMB in the spring of 2004. Therefore, the

fourth part of the collection system is the Medical Device Engineering Network (M–DEN)—a place on the MedSun software for the reporters to share information with each other.

In the **Federal Register** of January 27, 2004 (69 FR 3922), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Data Type	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
MedSun <sup>2</sup>	250	8	2,000	.75	1,500
M–DEN <sup>3</sup>	83	10	830	.50	415
Total					1,915

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection.

<sup>2</sup> MedSun means Medical Product Surveillance Network.

<sup>3</sup> M–DEN means Medical Device Engineering Network.

Currently, FDA has 180 sites participating in MedSun pilot program, but expects to have 250 sites over the next 2 years. The frequency of response reflects what FDA has actually been receiving as the average number of submissions in the MedSun Program. While six is the actual average for submissions, FDA hopes to increase this number to eight once their educational materials reach potential respondents. The time estimated to respond is based on feedback FDA has received from current MedSun reporters.

At this time, FDA estimates that one-third of the total number of respondents will access M–DEN aspect of the MedSun software, or approximately 83 persons per year. Each respondent is expected to post 5

problems and respond to 5 problems posted by other MedSun participants for a total of 10 responses per year. It is expected that each visit to the bulletin will not take longer than 30 minutes.

Dated: June 4, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**