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

0910-0471

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for clearance to continue to conduct the Medical Product Safety Network (MedSun), the national reporting system mandated by the Food and Drug Administration Act (FDAMA) of 1997.

This is an ongoing continuous data collection program.

Regulatory authority to collect this data: 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.

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(i)(b)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions; and 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 the FDA Modernization Act of 1997 (FDAMA) amended section 519(b) of the FD&C Act (21 U.S.C. 360i(b)). 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 the 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, implemented in 2002, was originally called the Medical Product Surveillance Network (MedSun), but now is called the Medical Product Safety Network (MedSun).

The program currently has 3 approved parts to the data collection: (1) collecting demographic profile information about the participating facilities; (2) implementing an electronic version of the portions of the MedWatch form (form FDA 3500A, OMB number 0910-0291, used to report adverse events occurring with medical devices; and (3)

adding additional voluntary questions to the data collection as FDA learns more about what information is needed to more fully investigate certain device problems.

2. Purpose and Use of the Information Collection

Use of MedSun reports: FDA relies on reports of product problems from consumers and health care professionals, as well as from device manufacturers, in order to understand if signals of product problems are emerging in the postmarket use environment. MedSun is a significant, and very successful, strategy used by FDA to understand problems with medical devices in use in hospitals and outpatient services associated with hospitals. The MedSun program is unique to FDA and provides FDA with the ability to have a dialogue with the clinical community, so they may work together to learn about, understand, and solve problems with the use of medical devices.

MedSun reports are triaged in the same manner as other reported device problems coming to FDA from other reporting sources, i.e., based on perceived risk to the patient. Some reports signal an immediate hazard, but more commonly it is the experienced FDA clinical staff who detect product problems, particularly those related to product use, through careful investigation of reported incidents and by searching for additional sources of information. The degree of perceived risk to the public is the most important consideration for any FDA public health action (product recall, Safety Alert, Public Health Notification, Action Team, Safety Tip, workshop, publication, etc.)

Clinical staff, epidemiologists, biomedical engineers and other FDA scientists access the MedSun reports to answer questions of risk assessment and to determine if there are signals which may indicate that actions may be needed to protect the public health. The MedSun reports have often been the initial signal to FDA that a problem was occurring with the use of a device in the clinical community. This has led to letters to manufacturers to learn more about the causes and solutions to the problems, led to Center Wide Workgroups to address the problems, Rapid Response Surveys, articles, and Public Health Notifications.

The MedSun reports are redacted and are placed nightly on the publicly available FDA MedSun website, and monthly on the FDA Manufacturer and User Facility Device Experience (MAUDE) website, so the public may view reports about problems with medical devices.

Consequences if data not collected: The MedSun program has provided a dimension to FDA's understanding of how, why, and when medical devices are used in the clinical community once the devices have been cleared for marketing, and the types of problems that occur once products are in widespread use. Before MedSun, FDA had little contact with the users of the medical devices, and the reports that were received from the clinical community were lacking in important details. Even though there is mandatory reporting for hospitals and other user facilities, under-reporting was a huge problem prior to MedSun. MedSun was specifically developed to overcome the under-reporting problem, at least from a subset of facilities in the country. FDA has come to rely on this excellent relationship with the clinical community. If MedSun is not permitted to continue, this valuable tool for information gathering will no longer be available to FDA.

The MedSun online system is currently approved and implemented by:

(1) Collecting demographic profile information. For the clinical sites we have recruited, we can obtain this information from the American Hospital Association (AHA). This data is used to provide FDA with a better understanding of the types and number of medical device problems that occur in specific types of facilities (e.g. academic versus non-teaching), and in certain size facilities (larger versus smaller facilities), etc.

(2) Implementing an electronic version of the portions of the 3500A form. The electronic version of the portions of the 3500A reduces the burden of reporting for the reporting community. Because the system is interactive, the report is easier to submit than the paper form 3500A. The name and address of the reporter is automatically filled in and drop-down lists appear when help is needed and only questions pertinent to the device being reported are asked. This electronic system also fulfills the Government Paperwork Elimination Act of 1998.

(3) Adding additional voluntary questions to the data collection. These questions are related to the type of medical device described in the report. FDA will use the answers to these questions to provide feedback to the facilities to help them improve internal quality systems to promote patient safety, and to gain important information to better understand the event and the potential risk to the public health. To date, participating sites routinely fill in these voluntary questions.

Over the years of collecting data, we have added questions to the questionnaire. These additions were all pre-approved by OMB. These questions relate mostly to specific devices. One set of questions pertains to tissue and cell products, and the other set of questions pertains to devices used in laboratories.

All of the questions that have been approved to date have been included in Attachment A – both those part of the 3500A form, and the additional questions approved. The "additional" questions are highlighted in yellow.

Respondents to this information collection include private sector for-profit businesses and not-for-profit institutions and Federal government.

3. Use of Improved Information Technology and Burden Reduction

The MedSun data collection has been an online data collection tool from its inception in 2002. The MedSun reporters access the reporting form at a secure Internet based website. They may type each report in separately or upload the data into the MedSun software from a file downloaded from their own internal systems – all through the same secure web site. The MedSun system complies with subpart B, § 1.11 (for closed systems) of 21 CFR part 11, where appropriate.

Our respondents tell us they greatly appreciate the ease of using our online tool. We get 99% of the MedSun reports online. The other 1% are taken over the phone or by fax when the either the MedSun site is having a software issue, or the MedSun site is down for maintenance.

4. Efforts to Identify Duplication and Use of Similar Information

No other part of the agency, federal government, or the public is systematically collecting medical device problem or adverse event data from a sample of user facilities.

5. Impact on Small Businesses or Other Small Entities

   None of the respondents are small businesses.

6. Consequences of Collecting the Information Less Frequently

   Respondents choose when and if they want to report and device problem, therefore reporting is occasional.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 1/19/2017 (82 FR 6566). No comments were received.

   Feedback from our participating sites is key to the success of this program. FDA analysts routinely talk with the reporting sites as part of the quality control/follow-up investigation of the reports sent into MedSun. The sites tell the analysts what aspects of the program need to be improved. Software enhancements to improve efficiency have been made to the application based on these comments.

9. Explanation of Any Payment or Gift to Respondents

   Respondents receive no payment for their participation in the MedSun program. Small reminders, to aid in prompting reporting, are provided during the sites' participation (e.g., posters for the sites to hang in areas where clinical staff will see them and badge cards for the healthcare professionals to wear that list the elements of a good report). These reminders are very important because the MedSun representatives are very busy people in their respective facilities and FDA is asking them to make time to contribute to the public health by reporting not only the mandatory device events (deaths and serious injuries), but also voluntary reports of 'close-calls' and 'potential for harm' events. Approximately 90% of the reports we receive in MedSun fall into the 'voluntary' category. These reports are extremely useful to FDA. They help the agency detect possible early problems with devices. It is important to the program to provide reminders to these busy reporters so they remember to send these voluntary reports. We spend approximately $32.00 per year per hospital on these reminders.

10. Assurance of Confidentiality Provided to Respondents

    FDA allows the participants in the MedSun project permission to use an alternative reporting mechanism, as granted under 21 CFR 803.19(c). Therefore, the participants in MedSun are afforded the same protections to confidentiality that they are currently afforded under the medical device mandatory reporting requirements (please see section 519(b) (2) and (b)(3) of the FD&C Act).

11. Justification for Sensitive Questions

Please see Confidentiality Section. The system collects the OMB cleared information of the age and weight of the patient (no names or social security numbers are collected). It collects the name, phone number, and work address of the reporter for the reporting site. None of this information is releasable to the public under the FD&C Act (section 519(b)(1)(D)(2)).

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
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	0.75	2,813

The burden estimate for the electronic reporting of adverse events is based on the number of facilities participating in MedSun (250). We estimate an average of 15 reports per site annually. We hope to reach this goal because FDA is working to promote reporting in general from the sites, as well as continuing to promote reporting from more specific parts of the hospital.

Therefore, this yields a total estimate of 3,750 annual responses (250 facilities x 15 data entries = 3,750 reports). The participating MedSun reporters tell FDA that it typically takes 20 to 45 minutes to fill out the online form. Using the high end of that timeframe, the overall annual burden hours will be 2,813 hours (3,750 report entries x 0.75 hours = 2,813 hours).

12b. Annualized Cost Burden Estimate

The primary MedSun representative in each hospital is a Risk Manager. It is anticipated that these representatives will complete the majority of the MedSun entries. The median range salary of this professional group is $56.26 per hour. The estimated annualized cost for MedSun respondents is 2,813 hours x $56.26 = $158,259 (rounded).

*Link for salary https://www.bls.gov/oes/current/naics4_622100.htm#11-0000, from the Bureau of Labor and Statistics Occupational and Employment and Wages data, May 2015 (occupation code 11-0000, Management Occupations was selected because there is no specific category for “Risk Managers of Hospitals”).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Risk Managers	2,813	$56.26	$158,259

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

    The current funding for the total MedSun project is approximately $3.5 million. This amount covers the cost of all aspects of this program. It covers not only the cost of the software data collection portion, it also covers the cost of the development of educational materials, of recruiting and orienting hospitals into the program, salaries for the FDA analysts who review and analyze the data in the reports, etc.

    The total cost of the MedSun project is related to the cost of 20 FDA full-time equivalent positions (FTEs), the small amount spent on the "reporting reminders," and the cost to maintain the system software.

15. Explanation for Program Changes or Adjustments

    This is a request for extension without change to the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

    This is a data collection system where reporters submit problems with medical devices when used in the clinical environment. All FDA collected adverse events about medical devices are posted on FDA websites. These reports are fully redacted according to Freedom of Information (FOI) and statutory requirements.

    FDA analysts also publish case study articles which refer to redacted reports received from the MedSun reporters.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    The OMB expiration date is currently displayed on the MedSun software landing page, and will remain there.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.