ADVERSE EVENT PROGRAM FOR MEDICAL DEVICES
(Medical Product Safety Network (MEDSUN))
0910-0471
SUPPORTING STATEMENT

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.

FDA has conducted this data collection as a pilot program from 2002 to present. The program has evolved over time and is successful. For purposes of the definition of a 'pilot data collection' under OMB, FDA is satisfied that the form of the program is complete and can be considered a program and we can drop the term 'pilot data collection.' 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 Food, Drug and Cosmetic Act (the 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 Food, Drug and Cosmetic Act (the act) (21U.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 act (Attachment A). 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 the Food and Drug

Administration (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 4 previously approved parts to the data collection: (1) collecting demographic profile information about the participating facilities; (2) Device Safety Exchange (DS-X), which is a place on the MedSun software for the reporters to share information with each other; (3) implementing an electronic version of the portions of the MedWatch form (form 3500A, OMB number 0910-0291, used to report adverse events occurring with medical devices; and (4) adding additional voluntary questions to the data collection as FDA learns more about what information is needed to more fully investigate certain device problems.

We discontinued the DS-X portion of the software (not widely used by the sites). They told us that they monitor list-serves for this type of communication and did not also have time to also monitor our website for the issue. The list-serves on the web draw far more comments than what we got from our 350 sites.

This data collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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 that detects product problems, particularly those related to product use, through careful investigation of reported incidents and 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, 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 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 wide-spread 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 on-line system is currently approved and implemented by:

(1) Collecting demographic profile information. For the hospitals and for most of the nursing homes we have recruited we can obtain this information from the American Hospital Association (AHA). However, we do ask a few of the nursing homes which were not listed with the AHA for this data. 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 8 years of collecting data, we have added questions to the questionnaire. These additions were all pre-approved by OMB. These questions relate to 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.

Attachment B lists all of the additional voluntary questions that have been approved to date.

(4) The Device Safety Exchange (DS-X) has been removed.

3. Use of Improved Information Technology and Burden Reduction:
The MedSun data collection has been an on-line data collection tool from its inception in 2002. The MedSun reporters access the reporting form at a secure Internet based web site. The MedSun system complies with Subpart B, 1.11, (for closed systems) of CFR 21 Part 11, where appropriate.

Our respondents tell us they greatly appreciate the ease of using our on-line tool. We get 99% of the MedSun reports on-line. 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

Some of the facilities enrolled in MedSun are small businesses. However, their participation has been voluntary, and will continue to be voluntary. Participants in our program have told us that using the Internet-based form is less burdensome than the paper form they previously used to submit reports. The impact of the program is the same for all the participating facilities, regardless of size.

6. Consequences of Collecting the Information Less Frequently:
Respondents choose when and if they want to report and device problem, therefore reporting is occasionally.

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 07/09/2010 (Vol. No. 75 FR 39535). There have been no comments to the June 2010 FR Notice which requested renewal of the MedSun program.

The 30-Day Notice also included that the Agency proposes to ask occasional questions of the MedSun sites, through the on-line reporting system, when reports indicate a signal that a possible public health emergency may be emerging. FDA did not receive any comments from that 30-Day Notice. On March 21, 2011, FDA staff spoke with OMB staff. OMB has instructed FDA to submit a separate Supporting Statement to request a generic tool to be cleared to use to ask these occasional questions of our MedSun sites. FDA will submit that request as a separate Supporting Statement.

Feedback from our participating sites is key to the success of this program. FDA analysts routinely talks 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.

AdvaMed, the association that represents medical device manufacturers, is supportive of the program. The one concern they expressed several years ago was that the MedSun contractor took too long in mailing the user facility report to the manufacturer. FDA quickly addressed this issue and the report is sent to the manufacturer before the report has undergone clinical review and follow-up investigation.

9. Explanation of Any Payment or Gift to Respondents:

Respondents receive no payment for their participation in the MedSun program. Small token reminders, to aid in prompting reporting, are provided during the sites' participation (i.e. MedSun coffee mug; pens; mouse pad, etc.). 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 $50.00 per year per reporter on these reminders. The total cost of the MedSun project is 5.1 Million dollars per year, but not all of this is for the data collection and report analysis that is the topic of this Justification (See number 14). Only about 265k is spent on the data collection tool – enhancements and maintenance.

The MedSun reporters are invited to an annual conference; the cost is part of the contract cost. This conference is critical to the success of the program. By fostering a 'team' approach among the reporting sites and FDA, the sites are encouraged to report and share the information with the agency and with one another in the program. FDA learns a great deal from the reporters when they come to the annual conference. We interact with them and learn what types of feedback are

the most useful in helping them promote patient safety. We provide an update about the MedSun program, showcase actions FDA has taken based on MedSun reports, and have educational presentations about medical devices.

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 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) parts (2) and (3) of the Act.

11. Justification for Sensitive Questions:
There are no questions of a sensitive nature.

12. <u>Estimates of Hour Burden Including Annualized Hourly Costs</u>

a. Annualized Hour Burden Estimate

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

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
MedSun facilities participating in the electronic reporting of adverse events program	400	15	6,000	45/60	4,500
Total hours					4,500

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

Explanation of burden for facilities participating in MedSun:

Derivation of numbers:
The burden estimate for the electronic reporting of adverse events is based on the number of facilities currently participating in MedSun (350 + smaller satellite hospitals =400). The current average number of reports per site is 8 reports annually, although we had been cleared for 15 reports in 2007. For purposes of this renewed data collection, we are again estimating 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 specific parts of the hospitals, such as the pediatric ICUs, electrophysiology laboratories, and the hospital laboratories.

Therefore, this yields a total annual responses of 6000 (400 facilities x 15 data entries = 6000 reports) the participating MedSun reporters tell FDA that it typically takes 20 to 45 minutes to fill out the on-line form. Using the high end of that time frame, the overall annual burden hours will be 4500 hours (6000 report entries X .75 hours = 4500 hours).

The DSX part of the reporting burden reflected in the 2007 renewal has been removed.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Risk Managers	4500	$44.00	$198,000.00

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 $103,000.00 per year, which is $44.00 per hour The estimated annualized cost for MedSun respondents is 4500 hours X $44 = $198,000.00. Link for salary – dated from October 2010 -- http://www1.salary.com/Risk-Management-Director-Healthcare-salary.html

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.

There is no record keeping burden to this data collection.

14. Annualized Cost to the Government

The current funding for the total MedSun project is $5.1 million dollars per year. 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.

Approximately $265,000.00/year of the 5.1M is spent on the total IT portion of the data collection. This includes programming costs for enhancements, time spent on planning and developing the enhancements, and time spent in Change Control Board meetings.

15. Explanation for Program Changes or Adjustments

Since the last approval in 2007, the burden estimate for this information collection is decreased 500 hours. The burden for putting reports into the system stays the same as in 2007, e.g. 4500 hours, while the 500 hour burden for the DS-X has been removed. Therefore, the 5000 burden hours approved in 2007, are now being adjusted down to 4500 hours.

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 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. Exemptions to Certification for Paperwork Reduction Act Submissions.
There are no exceptions to the certification.