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

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 a pilot project to evaluate aspects of a national reporting system mandated by the Food and Drug Administration Act (FDAMA) of 1997.

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).

This pilot has 4 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.

2. How, by Whom and For What Purpose the Information is to be Used

Reports are triaged 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 will access the MedSun database to answer questions of risk assessment and to determine if actions must be taken to protect the public health.

The MedSun reports will also be redacted and will periodically be placed on the publicly available FDA website so the public may view reports about problems with medical devices.

In addition to sending in specific reports of medical device problems, the Device Safety Exchange (DS-X) allows respondents to be able to share more general problems they were experiencing with devices at their site and get help in understanding the problem from the other participants in MedSun. For example, if a site's users were having trouble with a certain device, but there is 'no problem found' with the device when it is examined, the site might want to elicit suggestions on how to improve the correct use of the product, but wouldn't need to report this as an adverse event. This data will be used by the participating MedSun sites during the problem resolution process. When a solution is put forward to a problem, FDA will then post the problem and the solution on the FDA website for all health professionals to use.

Data collected from this MedSun pilot is aiding FDA in fulfilling its mission to monitor the safety and effectiveness of marketed medical devices as they are used in clinical settings and to determine what aspects of the pilot program should be implemented in the national program.

The system is 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: (a) Provide useful feedback to the reporting community. For example, once the sample is large enough, and there are enough reports in the database, FDA can provide the reporting facilities feedback that may be used by the facilities for benchmarking; and (b) 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 5 years of collecting data, we have added questions to the questionnaire. These additions were all pre-approved by OMB. These questions relate to specific devices. One set of new questions pertain to tissue and cell products, and the other set of questions pertain to devices used in laboratories. Additionally, a few of the original questions have been eliminated. The answers to these questions were found not to be particularly useful to FDA, so they were removed.

Attachment “A” lists all of the additional voluntary questions as well as notes as to which questions have been removed.

Throughout the pilot, FDA has encouraged the user facilities participating in the pilot program to suggest changes to the system. Only by refining the process during the pilot can FDA ensure that the final product, which will be implemented by regulation, will fulfill the needs of FDA and the reporting facilities. The final data collection instrument will be sent back for OMB approval during the regulation-promulgation process.

(4) The Device Safety Exchange (DS-X) allows respondents to be able to share more general problems they were experiencing with devices at their site and get help in understanding the problem from the other participants in MedSun**.**

3. To What Extent the Collection of Information involves the use of Automated, Electronic, Mechanical, or Other Technological Collection Techniques

The MedSun reporters access the reporting form at a secure Internet based web site. All data entry is done on-line. The MedSun system complies with Subpart B, 1.11, (for closed systems) of CFR 21 Part 11, where appropriate.

4. Describe Efforts to Identify Duplication

There is no similar effort occurring in the Agency

5. Small business

Some of the facilities enrolled in the MedSun pilot project are small businesses. However, for purposes of the pilot, their participation will 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 MedSun contractor supplies support to all participants, and will even enter the report for the site if the site wishes to call in the report or to send it on paper. The impact of the program is the same for all the participating facilities, regardless of size.

This program is for user facilities and is not for use by manufacturers. Manufacturers reporting requirements are unchanged.

6. Describe consequences to Federal program or policy if the collection is not conducted

FDA is mandated to replace universal user facility reporting of problems associated with medical devices with a national reporting system that includes a representative subset of user facilities. By conducting this pilot prior to implementing the national system by regulation, FDA will be able to adjust and improve aspects of the reporting system, and thus avoid costly and time consuming changes to the system implemented by regulation before it has been fully tested.

7. Special Circumstances

There are no special circumstances that apply to this information collection.

8. Describe efforts to consult with person outside the agency to obtain their views on the availability of data, etc.

In the Federal Register of June 13, 2007 (72 FR 32670), FDA published a 60 day notice asking for comments on this information collection (Attachment C). There are no comments.

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

We conduct an annual customer satisfaction survey, approved under OMB control number 0910-0360, of the MedSun reporters to ascertain the usefulness of the incentives we offer as part of the program. The responses indicate that the reporters find the program very useful.

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 contractor now sends the report 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; mousepad, 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 4.9 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).

The 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 will grant the participants in the pilot project permission to use an alternative reporting mechanism, as granted under CFR 803.19(c). Therefore, the participants in this pilot program 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

None of the questions will be sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

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

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 519(b) of the Food, Drug and Cosmetic Act (the act) (21U.S.C. 360I(b)) Facilities participating in the electronic reporting of adverse events program	400	15	6,000	.75	4,500
Section 519(b) of the Food, Drug and Cosmetic Act (the act) (21U.S.C. 360I(b)) Facilities participating in DS-X	200	5	1,000	.50	500
Total hours					5,000

[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) and the number of sites (50) expected to be added to the program over the next 3 years. The current average number of reports per site is 7 reports annually. For purposes of this renewed data collection, we are estimating an average of 15 reports per site annually. This increase is expected since MedSun is working to promote reporting in general from the sites, as well as promoting 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).

Determining burden for the DS-X portion of MedSun: Not all sites use this part of the software. Past use of the site has been low, so efforts are underway to increase participation. Therefore, it is hopefully anticipated that 200 participants will access the DS-X portion of MedSun. Of these 200 participants, it is anticipated that each will use the site 5 times. To determine the total annual responses for DS-X: 200 participants multiplied by 5, the number of times each will access DS-X, yields annual responses of 1000 reports.

It typically takes an average of 30 minutes to enter data into DS-X, given that there are various types of data entries which are possible, some of which are more lengthy than others. The number of burden hours for DS-X is determined by multiplying the expected 1000 times the site will be accessed by the average amount of time it takes to make a DS-X data entry (30 minutes). This equals a burden of 500 hours.

The total burden is derived from the 4500 hours for MedSun reports and the 500 hours for DS-X entries, which equals 5000 burden hours.

13. Estimate of Other Total Annual Cost Burden to Respondents

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

14. Annual Cost to the Federal Government

The current funding for the total MedSun project is $4.9 million dollars per year. This money has been awarded as a Task Order contract. This contract covers the cost of all aspects of this program. It covers not only the cost of the data collection portion, it also covers the cost of the development of educational materials, of recruiting and orienting hospitals into the program, etc. While it is difficult to separate out the exact cost of the

data collection portion of the contract, which involves all the IT costs, all the review and analysis and follow-up to the reports received, etc., the approximate cost for the portion of the contract which goes to the data collection described in this Justification is 2.8 million.

15 Explanation for Program Changes or Adjustments

Since the last approval in 2004, the burden estimate for this information collection increased by 2,320 hours. This increase is because more sites have been enrolled in MedSun and MedSun is working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric ICUs, electrophysiology laboratories, and the hospital laboratories.

There have been 2 sets of questions which have been added, following OMB approval. These additions were required to gain important information about reported problems with certain medical products – tissues and cells, and laboratory devices. Also, a few questions were eliminated. The burden of 45 minutes per report remains unchanged because the new questions are only for a small portion of reports and do not add much time to the data collection..

16. Plans of Tabulation and Publication and Project Time Schedule

The contractor will tabulate findings in an annual report to FDA. There is no plan to publish that data.

17. Reason Display of OMB Expiration Date is Inappropriate

The OMB number and expiration date will be listed on the first screen in the web-based form.

18. Exemption to Certification for Paperwork Reduction Act Submissions

No exemptions requested.