SUPPORTING STATEMENT FOR ADVERSE EVENT PILOT PROGRAM FOR MEDICAL DEVICES (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. This collection was first approved by OMB on July 11, 2001 (OMB No: 0910-0471- expiration date: 07/31/2004).

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 Sec. 519(b)(5)(A) of the act. 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 is called the Medical Product Surveillance Network (MedSun).

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 three years. Data collection began in February 2002 and has been increasing since that time. We have achieved our recruitment goals each year, reaching 180 sites at the end of FY 2003. We 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 we have gained a national reputation, with hospitals waiting in line to join. However, our current resources will not permit us to expand beyond 250 sites.

The facilities that will be added this year will be primarily from the west coast – we have been staging our expansion westward. Since we will only reach our full complement of 250 sites, spread across the continental U.S., by the end of FY2005, we plan to stay in the pilot phase for several more years. We must evaluate the types of reports we receive from the full complement before we can determine the type of sample composition we will propose in a regulation and we must study the most effective means of encouraging reporting before we can promulgate a successful regulation.

This pilot originally had 3 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 3500A, OMB number: 0910-0291) used to report adverse events occurring with medical devices: (3) adding additional voluntary questions to the data collection. To date, these 3 features remained unchanged. However, there has been an addition to the data collection that was approved by OMB in the Spring of 2004. Therefore, the 4th 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.

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

The data captured in the MedSun Internet database is analyzed by FDA in the same manner as the data that comes to the agency in the form of 'paper' adverse event reports sent by user facilities not in MedSun and by manufacturers (these paper reports are in a different database). That is, 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, Ad Hoc Committee, 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.

NEW ADDITION to the website: OMB approved an adjustment to the data collection in Spring 2004 – the Medical Device Engineering Network (M-DEN). Our site reporters requested we make an addition to the data collection. In addition to sending in specific reports of medical device problems, the reporters wanted 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. The original OMB justification stated that we would ask the sites for this data. We have found that for the hospitals and for most of the nursing homes we have recruited we can obtain this information from the American Hospital Association (AHA), so we do not ask most of the sites for this data. However, we did need to 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. This 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.

These questions were pre-tested before the program began collecting data in 2002. Nine facilities volunteered to help FDA in designing a user-friendly interactive web-site and to advise FDA as to what types of questions they would like to answer, and in turn be able to use the answers to perform analytical searches, regarding adverse events.

Please see Attachment B for a list of these additional voluntary questions. These remain unchanged from the initial OMB approval.

(4) **NEW ADDITION:** Medical Device Engineering Network (M-DEN): See description, above, under NEW ADDITION to the website.

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.

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

FDA is seeking approval to continue implementing the MedSun electronic, Internet-based interactive system for use by those facilities selected to participate in the pilot project. The MedSun system complies with Subpart B, 1.11, (for closed systems) of CFR 21 Part 11, where appropriate (it does not meet specifications for electronic signatures since these are not signed records).

Once the regulation is promulgated for implementing the elimination of the universal user-facility reporting system and replacing it with a "subset" of reporting facilities, this electronic system will also fulfill the Government Paperwork Elimination Act of 1998.

4. Describe Efforts to Identify Duplication

FDA does not have any other Internet reporting system in place for use in capturing data on the 3500A form for use by user facilities when sending in reports relating to adverse events associated with medical devices or for sharing product experiences. Therefore, there is no duplication of effort.

5. Small business

Some of the facilities enrolled in the pilot project will be 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

No special circumstances.

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

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 changes have been made to the application based on these comments. For example, a 'save' function has been implemented so the reporters can save long event descriptions in case they are disconnected from the system, and an improved 'print' function has been developed.

Additionally, formal feedback has also been obtained. We recently conducted a customer satisfaction survey (OMB No: 0910-0360; expiration date: 3/31/05) of the MedSun reporters to ascertain the usefulness of the incentives we offer as part of the program. This survey was sent out in July 2003 and we received a 71% response rate. The responses indicated that the reporters are finding the program very useful.

FDA met with AdvaMed, the association that represents medical device manufacturers, on November 10, 2003 to discuss the MedSun program. The AdvaMed members are supportive of the program. The one concern they expressed is that the MedSun contractor sometimes takes too long in mailing the user facility report to the manufacturer. FDA has addressed this issue and the contractor will now send the report to the manufacturer before the report has undergone clinical review and follow-up investigation. The previous 'hold-up' was taking place because FDA has tasked the contractor with obtaining as a complete report as possible from the site before it is released to FDA. The contractor was performing this service before sending it both to FDA and the manufacturer. The manufacturers prefer to have the report earlier, and they will perform their own follow-up.

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 reporters are invited to an annual conference. 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 and showcase actions FDA has taken based on MedSun reports. In order to improve the program, we provide interesting presentations to train the reporters to recognize and report problems with 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[1]

For MedSun Adverse Event Reporting

# of Respondents	Annual Frequency of Respondent	Total Annual Responses	Hours/ Responses	Total Hours
350	8	2800	.75	2100

[1]There are no Operating and Maintenance Costs nor Capital Costs associated with this collection of information.

For Medical Device Engineering Network

# of Respondents	Annual Frequency of Respondent	Total Annual Responses	Hours/ Responses	Total Hours
116	10	1160	.50	580

[1]There are no Operating and Maintenance Costs nor Capital Costs associated with this collection of information.

Derivation of numbers for burden chart:

For the first chart "MedSun Adverse Event Reporting": We have updated (increased) the number of respondents because we now have many more sites participating in the program. Currently, we have 265 sites, but over the next two years we will reach a total of 350 sites. Therefore, in this submission, we will increase from the original number that was used (83) which was an average of the number of sites to be enrolled throughout the program, and we will use the more conservative number of the final total of sites -- - 350. The original annual frequency of response was based on FDA's experience with its mandatory and voluntary reporting systems. We are changing this number in this submission to more accurately reflect what we have actually been receiving as the average number of submissions in the MedSun program. Six is the average, but we are using 8 for this submission because we are hopeful that educational materials we are developing will be successful in increasing reporting The time it will take to fill out the electronic 3500A form is based on the feedback we have received from the MedSun reporters.

Annualized Hourly Costs for the MedSun reports

Risk managers working in hospitals will complete the majority of the surveys. The average salary of this professional group is $32.00 per hour (source: ASRHM Web Page, "1998 Compensation Survey Results."). The estimated annualized annual cost for 2100 hours of reporting time is $67,200.00.

For the second chart, "Medical Device Engineering Network (M-DEN)": At this time we estimate that one-third of the total number of respondents will access the M-DEN aspect of the MedSun software – that equals approximately 116 persons per year. Each person is expected to post 5 problems and respond to 5 problems posted by other MedSun participants – for a total of 10. The 116 persons X the 10 visits equals the 1160 visits to the Bulletin per years. It is expected that each visit to the Bulletin will not take longer than 30 minutes. This equals burden hours (1160 X .50 = 580).

Annualized Hourly Costs for the Medical Device Engineering Network (M-DEN):

Using the same figures for risk managers cited, above, the estimated annualized cost for 580 hours of reporting time is $18,5680.00.

13. Estimate of Other Total Annual Cost Burden to Respondents

There will be no other costs incurred by respondents.

14. Annual Cost to the Federal Government

The base funding for MedSun has been increasing over the past three years. The current funding for the MedSun project is $4.5 million dollars per year. This money has been awarded as a Task Order contract.

15. Explanation for Program Changes or Adjustments

There is a program adjustment that was implemented following OMB approval. In addition to sending reports to MedSun, the reporters have requested that we also offer a 'problem sharing' aspect of the program. This aspect is also Internet based and the users enter the option through the MedSun software. The reporters can post general device problems they are experiencing at their facility and the other MedSun reporters can view the problem and offer advice/solutions. This problem sharing aspect of MedSun, called M-DEN, is reflected in the new burden chart in number 12, above.

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.

B. Collection of Information Employing Statistical Methods

1. Potential Respondent Universe and Sample Selection Method

The potential respondent universe includes 7,000 hospitals, 17,000 nursing homes, and approximately 20,000 "other" types of health facilities (outpatient treatment centers, outpatient diagnostic centers, emergency health services, and home health services). Since denominator data is unknown for the number and types of incidents that occur with medical devices in the United States, FDA will not use the data collected to make national estimates of devices problems, use problems, etc. In considering the selection of facilities to participate in the pilot, it is important to understand that the main purpose of the eventual, national device surveillance network is not to make precise statistical estimates of frequency of occurrence of adverse medical device events. The purpose of this postmarket surveillance is to obtain signals that problems are occurring and to learn as much as possible about the incidents.

Therefore, it is imperative that facilities be selected that are willing to work closely with FDA to establish a program that generates the types of signals that will enable FDA to take timely action to protect the public health. The greatest participation, and thus the best signals, will be obtained from facilities which have organizational structures and cultures that are willing to share information with the outside world in the interest of increased patient safety. FDA initially recruited those large hospitals that had already expressed interest in joining the program and had national reputations for developing strong patient safety programs. We also recruited some nursing homes in the first year. We are now also in the process of recruiting those larger hospitals that fall into our targeting recruiting region that are part of the American Hospital Association database. These larger hospitals often have other types of adjunct facilities as part of the organization – such as long-term care facilities (similar to nursing homes), outpatient treatment centers, outpatient diagnostic centers, and home health agencies. Larger institutions are also more apt to have experience with diverse medical devices and, given the volume of patients that is admitted each year, are also more likely to have adverse events occur with those medical devices. The types of facilities which will make the most use of the system are in the best position to evaluate the user-friendliness and burden aspects of the system. The usefulness of the database and the search engine for both FDA and the facilities will be best evaluated if we can maximize the number of

reports submitted. Therefore, the probability of obtaining input into the system so the system may be tested and refined is greater if larger institutions are enrolled.

Enrollment into the pilot will be voluntary.

2. Information Collection Procedures

The facilities will be invited to participate in the pilot project. If they agree to participate, they will sign a Memorandum of Participation which describes the reporting procedure they will be expected to complete (send adverse event reports via the web – both mandatory and voluntary reports; fill in additional questions; and provide FDA with feedback on the usability of the system).

Each facility will receive training in how to participate in the pilot prior to submitting adverse event reports. The facilities will report incidents of adverse events via the Internet-based reporting system to FDA via a contractor. The facility will answer the questions that currently appear on the 3500A form as well as some additional questions. The contractor will review the reports for completeness and will follow up with the facility as needed to ensure the report answers the question, "What happened to cause the adverse event?" before the report is made available to FDA.

The contractor will also contact each facility as needed to ascertain why any of the additional voluntary questions were left unanswered. These comments will be collected and analyzed using descriptive statistics. The system will be revised according to the types of comments received.

3. Methods to Maximize Response Rates

Every effort will be made to maximize responses. However, in postmarket surveillance that is based on numerator, rather than denominator, data, obtaining important signals that problems may be occurring is more critical than obtaining large numbers of reports.

Facilities will continue to use the Internet-based system to report adverse events. FDA's postmarket medical device adverse event reporting is a passive system. It requires individuals working within a facility to recognize that an adverse event was related to the use of a medical device and to report that incident through the appropriate channels within that facility. The person designated with the job of fulfilling regulatory requirements for the hospital must then send the report to FDA. Therefore, while FDA will train each facility in the mechanisms of reporting, facilities will only forward reports if an adverse event occurs, or the potential for an adverse event occurs, that is related to a medical device. It is impossible to predict how many adverse events will occur per year at each facility during the pilot. Our original prediction was that an average of 15 reports per year would be sent by each facility. However, based on current collection rates, FDA has refined that prediction to an average of 8 reports per facility per year. If a facility has sent less than 2 reports in the first 6-months of entering the pilot, the contractor will call the facility contact person to ask how the system seems to be working, if the facility

needs more training in the mechanics of working in the pilot project, etc. This gentle probing is to remind the facility contact person that the success of the project depends on each facility forwarding all medical device related adverse events.

Facilities will voluntarily fill in answers to data fields not currently included in the 3500A form. To encourage the facilities to fill in these data elements, the contractor will, on an intermittent basis, call the facility contact person to ascertain the reason the items were not filled in. The responses given by the contact person will aid FDA in determining if the facility does not believe the data collected by the questions will provide useful information to them when FDA provides feedback to the respondents about that data element, the answers to the questions are too difficult for the facility to find in a timely manner, or the facility is not comfortable, for whatever reason, in providing the answers. By understanding why facilities may be reluctant to fill in the answers to additional questions, FDA will be able to design a user-friendly, useful final product for use by the national system.

4. Test of Procedures

The need for user facilities to report adverse events associated with medical devices is currently mandated by law, so the fundamental mechanics of how to work with a reporting program is well-known to facilities. Before MedSun, all reporting had been a paper system, so this pilot is the first test of a new electronic version. Thus, when FDA is ready to implement a national reporting system and submits to OMB for clearance to implement that project, FDA will discuss the experience gained from this pilot, as this is the "test for procedures" for the national Medical Product Surveillance Network (MedSun) reporting program.

5. Statistical Consultation and Independent Review

CODA, the contractor tasked with developing and implementing the MedSun program, assisted FDA in determining the design of the data collection.

CODA
1100 Wayne Ave.
Suite 750
Silver Spring, MD 20910 301-588-0177
Doris Northrup, President