UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control No. 0910-0471

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, the agency, us or we) Medical Product Safety Network (MedSun) program, a national reporting system mandated under the Food and Drug Administration Modernization Act (FDAMA) of 1997 to collect data regarding medical device reports associated with medical device related deaths, serious injuries, and malfunctions. Provisions in section 213 of FDAMA amended section 519(b) of the FD&C Act (21 U.S.C. 360i(b)), to require universal user facility reporting with a system limited to a *"…subset of other user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries*." The MedSun program includes three primary data collection components:

(1) demographic profile information about the participating facilities;
(2) portions of information participating facilities are already mandated to report regarding adverse events; and
(3) additional voluntary questions.

Accordingly, we are requesting extension of OMB approval for the information collection provisions included in our MedSun program and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We rely 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 us with the ability to have a dialogue with the clinical community and work together to learn about, understand, and solve problems with the use of medical devices in the clinical setting.

MedSun reports are triaged in the same manner as other reported device problems 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. 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.

3. Use of Improved Information Technology and Burden Reduction

The MedSun data collection is an internet-based data collection system. The MedSun reporters access the reporting form at a secure internet-based website (see https://medsun.fda.gov/FDA/). 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 receive 99% of the MedSun reports online. The remaining 1% is 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

We are unaware of duplicative information. Although we maintain other information collection associated with adverse events, this collection specifically aligns with statutory objectives for data assessment associated with medical device product use.

5. Impact on Small Businesses or Other Small Entities

There is no undue burden imposed on small entities who may be subject to the information collection. At the same time, we provide resources to small businesses on our website, along with staff to assist small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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), we published a 60-day notice for public comment in the Federal Register of September 20, 2019 (84 FR 49526). One comment was received. The comment suggested expanding the MedSun program and making compulsory reporting of all issues. 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 those reporting 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

This ICR collects personally identifiable information (PII) or information of a personal nature. Information is collected via FDA Form 3500A (MedWatch – The FDA Safety Information and Adverse Event Reporting Program - Mandatory). PII collected is name, address, patient

identifier, telephone number, email address, age, gender, date of birth (DOB), race, and ethnicity. This ICR is collecting medical device report information from hospitals participating in MedSun. Most data elements collected describe adverse events or potential for harm events (e.g. near misses) associated with medical devices and experienced at hospitals. PII is redacted.

FDA determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

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

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature. 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

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Adverse event reporting	300	18	5400	0.5	2,700

The burden estimate for the electronic reporting of adverse events is based on the number of facilities participating in MedSun (300). We estimate an average of 18 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 5,400 annual responses (300 facilities x 18 data entries = 5,400 reports). The participating MedSun reporters tell FDA that it typically takes 30 minutes to fill out the online form. Therefore, the overall annual burden hours will be 2,700 hours (5,400 report entries x 0.5 hours = 2,700 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 $57.95 per hour. The estimated annualized cost for MedSun respondents is 2,700 hours x $57.95 = $156,465.

*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 2018 (occupation code 11-9111 Medical and Health Services Managers, General Medical and Surgical Hospitals 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	2,700	$57.95	$156,465

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

Our estimated burden for the information collection reflects an overall decrease of 113 hours despite a corresponding increase of 1,650 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years but a decrease in the amount of time spent entering data due to IT efficiencies that have been built into the MedSun reporting system to reduce data entry by user facilities.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.