U.S. Food and Drug Administration
Postmarket Surveillance of Medical Devices
21 CFR Part 822
OMB Control Number 0910-0449

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 to continue information collection requirements in 21 CFR Part 822.

Section 522 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360l) authorizes the FDA to require manufacturers to conduct postmarket surveillance of any device that meets the criteria set forth in the statute.

We therefore request OMB extension of postmark surveillance of medical device provisions found in 21 CFR Parts 822 and recordkeeping requirements as discussed in this supporting statement.

Reporting:

Postmarket surveillance (PS) submission (21 CFR 822.9 and 822.10)
Specifies the contents of a postmarket surveillance (PS) plan, information about the person designated to conduct the surveillance, and organizational/ administrative information.

Changes to PS plan after approval (21 CFR 822.21)
Specifies the procedures for making changes to the postmarket surveillance plan after it is approved.

Changes to PS plan for a device that is no longer marketed (21 CFR 822.28)
Manufacturers may request that the postmarket surveillance be terminated or modified if the manufacturer ceases marketing of a device subject to postmarket surveillance.

Waiver (21 CFR 822.29)
Specifies procedures for requesting a waiver of any requirement of the regulation.

Exemption request (21 CFR 822.30)
Specifies procedures for requesting exemption from the requirement to conduct PS.

Periodic reports (21 CFR 822.38)
Requires submission of periodic reports as specified in the PS plan and other information as needed.

Recordkeeping:

Manufacturer records (21 CFR 822.31)
Specifies records that must be maintained by the manufacturer to ensure that the PS is conducted in accordance with the approved plan.

Investigator records (21 CFR 822.32)
Specifies records that must be maintained by investigators participating in the PS study.

2. Purpose and Use of the Information Collection

The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The PS regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with 21 CFR part 822 in §§ 822.15 to 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. If this information is not collected, the FDA cannot ensure that the PS will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products. All the respondents are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

FDA believes that the PS regulation is flexible enough to allow for improved technology for data collection.

The Electronics Signature Regulation (eSig) (21 CFR Part 11), which became effective August 20, 1997, permits FDA to accept documents or portions of regulatory applications in electronic format in lieu of paper.

All of the respondents to the information collection may use computer word processing, electronic forms, spreadsheet, and database software to collect and format information for submission to FDA. While prepared using electronic means, the prepared submissions are typically sent via paper mail. During the review of a PS Plan, reviewers work interactively with the manufacturers who can submit files electronically in response to review requests, as well as for interim and final reports. In addition, the flexibility in the PS regulation is intended to allow manufacturers to use their existing information technologies whenever possible. The use of electronic forms of recordkeeping and reporting submissions to FDA remains voluntary.

FDA has attempted to maximize current technology to reduce burden for respondents by the methods mentioned above. FDA will continue to pursue methods of applying technology to reduce burden to the respondents of its information collections.

4. Efforts to Identify Duplication and Use of Similar Information

The statute authorizes the FDA to use discretion in determining whether or not to order a manufacturer to conduct postmarket surveillance of a device. It is the intent of the FDA to impose postmarket surveillance only when information needed to address a public health surveillance issue is not otherwise available. Under these circumstances, information specific to the issue and the device cannot be obtained from any source other than the manufacturer; therefore, this effort is not duplicated elsewhere.

No similar data are available to or collected by FDA because each PS plan is device and public health issue-specific.

5. Impact on Small Businesses or Other Small Entities

The reporting and recordkeeping requirements required by this information collection are the same for all firms, regardless of size. The FDA exercises caution and discretion when implementing additional recordkeeping and reporting requirements. The FDA recognizes that submission of this data may be a hardship for small businesses, but every business, regardless of size, should provide data or other information necessary to protect the public health when a postmarket surveillance issue has been identified.

During postmarket surveillance actions, FDA has provided guidance and then worked directly with the firms to provide specific direction as to what information was needed to lessen the impact for each firm and continue to protect the health and safety of the public.

FDA offers the resources of the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE). DICE's staff provides technical and other nonfinancial assistance to small firms expressly to aid them in complying with the requirements of the FD&C Act, including providing assistance with identifying ways manufacturers can avoid postmarket surveillance actions through the use of least burdensome practices. The activities of DICE include participating in and presenting conferences, workshops, and seminars on the application and interpretation of relevant regulations, consulting with individual firms/sponsors, and development and dissemination of educational materials. Staff is available to respond to questions and a toll-free telephone number was established to facilitate this communication link.

6. Consequences of Collecting the Information Less Frequently

As required by 21 CFR Part 822, manufacturers submit:

- PS reports on an annual or semi-annual basis, as specified in the approved PS plan
- PS supplements and other submission types (e.g., changes in ownerships, waivers, exemptions) occasionally.

The FDA will use its authority to require a manufacturer to conduct postmarket surveillance in response to a specific public health issue. The consequence of collecting

the information less frequently would be an inability to make decisions and take action to protect the public health. There are no legal obstacles to reduce the burden.

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 June 19, 2019 (84 FR 28554). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    This ICR collects personally identifiable information (PII) and information of a personal nature. Section 522 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360l) authorizes the FDA to require manufacturers to conduct post-market surveillance of any device that meets the criteria set forth in the statute. PII collected with submissions include name, address, telephone number, and experience/qualifications. PII is collected in the context of the individual's professional capacity.

    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.

    Section 822.23 states that we consider the content of postmarket submissions confidential until we have approved the postmarket surveillance plan. After we have approved the plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed in accordance with the Freedom of Information Act (FOIA). We will continue to protect trade secret and confidential commercial information after the plan is approved. Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b) (1-9)). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. We will not disclose information identifying individual patients. Respondents may indicate in their submission which information they consider trade secret or confidential commercial.

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as those regarding sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Postmarket surveillance submission (822.9 and 822.10)	25	1	25	120	3,000
Changes to PS plan after approval (822.21)	9	1	9	40	360
Changes to PS plan for a device that is no longer marketed (822.28)	6	1	6	8	48
Waiver (822.29)	1	1	1	40	40
Exemption request (822.30)	16	1	16	40	640
Periodic reports (822.38)	25	3	75	40	3,000
Total					7,088

Table 2.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Manufacturer records (822.31)	25	1	25	20	500
Investigator records (822.32)	75	1	75	5	375
Total					875

Explanation of Reporting Burden Estimate:
The burden captured in Table 1 is based on the data from FDA's internal tracking system.

Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because "it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument." (5 CFR 1320.3(h)(1))

Explanation of Recordkeeping Burden Estimate:
FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year

clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with postmarket surveillance.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate uses an average wage rate based on data from the Bureau of Labor and Statistics' May 2018 National Occupational Employment and Wage Estimates United States (http://www.bls.gov/oes/current/oes_nat.htm) for the following occupations: Operations Specialties Managers ($63.79/hour; occupation code 11-3000), Administrative Services Managers ($50.99/hour; occupation code 11-3011), and General and Operations Managers ($59.56/hour; occupation code 11-1021).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Respondent	7,963	$58.11	$462,730

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

FDA estimates that an average of 3 full time equivalents (FTEs) reviewing and processing the postmarket surveillance information. Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $810,915.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects a decrease of 29,982 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information for statistical use.

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.