Supporting Statement for
Postmarket Surveillance
(21 CFR 822)

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting approval of information collection requirements in 21 CFR Part 822 as set forth in the proposed rule (Attachment A).

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

21 CFR 822.8 – Reporting

Specifies the contents of a Postmarket Surveillance (PS) submission, including the plan, information about the person designated to conduct the surveillance, and organizational/ administrative information.

21 CFR 822.9 – Reporting

Specifies the information to be included in the PS plan.

21 CFR 822.20 - Reporting

Specifies the procedures for making changes to the postmarket surveillance plan after it is approved.

21 CFR 822.26 – Reporting

Requires notification to the FDA is going out of business.

21 CFR 822.27 – Reporting

Requires submission of changes to PS plan for FDA approval in the event that the manufacturer ceases marketing of a device subject to postmarket surveillance.

21 CFR 822.28 – Reporting

Specifies procedures for requesting a waiver of any requirement of the regulation.

21 CFR 822.29 – Reporting

Specifies procedures for requesting exemption from the requirement to conduct PS.

21 CFR 822.30 – Recordkeeping

Specifies records that must be maintained by the manufacturer, to ensure that the PS is conducted in accordance with the approved plan.

21 CFR 822.31 – Recordkeeping

Specifies records that must be maintained by investigators participating in the PS.

21 CFR 822.33 – Reporting

Requires notification to the FDA in the event of transfer of records to a new manufacturer or investigator.

21 CFR 822.37 – Reporting

Requires submission of periodic reports as specified in the PS plan and other information as needed.

2. Purpose and Use of the Information

This Postmarket Surveillance regulation establishes procedures that FDA uses to approve and disapprove Postmarket Surveillance plans. The PS regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with 21 CFR 822.15 – 18 (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.

3. Use of 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.

Respondents to FDA information collections may use computer word processing, electronic forms, spreadsheet, and database software to collect and format information for submission to FDA. FDA has reduced the burden of responding to regulatory statute through the use of these electronic applications, their Fax-on-Demand fax back system, their Electronic Docket, and the Internet. . 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 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.

In addition, the FDA anticipates that fewer than 100 manufacturers will be required to initiate postmarket surveillance each year. Based on past experience with postmarket surveillance, most of these will be large businesses. Therefore, the FDA does not expect that the information collection will have a significant impact on a substantial number of small businesses.

6. **Consequences of Collecting the Information Less Frequently**

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.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The information collection in the postmarket surveillance regulation is consistent with 5 CFR 1320.5.

8. **Outside Consultation**

Publication of this proposal will provide an opportunity for persons outside the agency to offer their comments on the proposed information collection.

9. **Explanation of Any Payment or Gift to Respondents**

This regulation does not provide any payment or gift to respondents.

10. **Assurance of Confidentiality Provided to Respondents**

The regulation states that trade secret and commercial confidential information will be considered confidential. All other contents of the original application, amendments, supplements, and reports may be disclosed in accordance with the Freedom of Information Act (FOIA).

11. **Justification for Sensitive Questions**

This information collection does not concern questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs or other matters considered private.

12. **Estimates of Hour Burden Including Annualized Hourly Costs**

Table 1 provides an estimate of the annual reporting burden for manufacturers required to conduct postmarket surveillance. An explanation of the hour burden estimate follows the table and an explanation of the total cost estimate is provided in item 13 below.

Table 1 – Estimated Annual Reporting Burden[1]

CFR Section	No. of Respondents	No. of Responses	Total Annual Responses	Hours per Response	Total Hours
822.8, 822.9	30	1	30	120	3,600
822.20	7	1	7	40	280
822.26	1	1	1	8	8
822.27	3	1	3	40	120
822.28	5	1	5	40	200
822.29	1	1	1	120	120
822.37	5	1	5	20	100
822.37	90	2	180	80	14,400
Total					18,828

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

Table 2 – Estimated Annual Recordkeeping Burden[1]

CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Records	Total Hours
822.30	90	1	90	20	1,800
822.31	270	1	270	10	2,700
Total					4,500

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

Explanation of Reporting Burden Estimate

The FDA has had limited experience with postmarket surveillance under SMDA, and the FDAMA significantly modified the provisions of section 522. Based on current staffing and resources, we anticipate that we will issue postmarket surveillance orders for six (6) generic devices, each with approximately five (5) manufacturers. Each of these manufacturers will be required to submit a postmarket surveillance plan (21 CFR 822.8, 822.9) and interim and final reports on the progress of the surveillance (21 CFR 822.37). We anticipate that we may, on a case-by-case basis, request additional information from a manufacturer. We anticipate that a small number of respondents will propose changes to their postmarket surveillance plans (21 CFR 822.20), request a waiver of a specific requirement of this regulation (21 CFR 822.28), or request exemption from the requirement to conduct postmarket surveillance of their device (21 CFR 822.29). Our experience has shown that a few respondents will go out of business (21 CFR 822.26) or cease marketing the device subject to postmarket surveillance (21 CFR 822.27) each year. In addition, manufacturers must certify transfer of records when ownership changes (21 CFR 822.33).

Section 822.25 does 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." (21 CFR 1320.3(h)(1).

Explanation of Recordkeeping Burden Estimate

We expect that at least some of the manufacturers will be able to satisfy the postmarket surveillance requirement using information or data they already have. For purposes of calculating burden, however, we have assumed that each postmarket surveillance order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on our knowledge and experience with limited implementation of section 522 under SMDA. Therefore, three years after implementation, we would expect that the recordkeeping requirements would apply to a maximum of 90 manufacturers (30 added each year) and 270 investigators (three per surveillance plan). After three years, we would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued.

13. **Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

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

14. **Annualized Cost to the Federal Government**

FDA estimates that approximately 9.5 staff-years will be devoted to this activity annually, at a cost of $ 788,500.

15. **Explanation for Program Changes or Adjustments**

This is a new collection.

16. **Plans for Tabulation and Publication and Project Time Schedule**

Not applicable.

17. **Reason(s) Display of OMB Expiration Date is Inappropriate**

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. **Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB for 83-I have been identified.

B. Collection of Information Employing Statistical Methods

There are no plans to publish the information collected under the provisions of this proposed regulation for statistical use. The collection of information that is required under the provisions of this proposed regulation does not employ statistical methods.