SUPPORTING STATEMENT
FOR
POSTMARKET SURVEILLANCE
(21 CFR 822)
OMB No. 0910-0449

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting approval to continue information collection requirements in 21 CFR Part 822 (Attachment 1).

Section 522 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(a)) (Attachment 2) 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 822.9 – 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 822.10 – Reporting

Specifies the information to be included in the PS plan.

21 CFR 822.21 - Reporting

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

21 CFR 822.27 – Reporting

Requires notification to the FDA when a firm is going out of business.

21 CFR 822.28 – 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 822.29 – Reporting

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

21 CFR 822.30 – Reporting

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

21 CFR 822.31 – 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 822.32 – Recordkeeping

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

21 CFR 822.34 – Reporting

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

21 CFR 822.38 – 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 (PS) 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, the Fax-on-Demand fax back system, the 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 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.

In addition, the FDA anticipates that fewer than 30 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.

During the past three years, 5 postmarket surveillance actions were conducted by FDA. FDA 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.

In addition, FDA operates the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) in the Center for Devices and Radiological Health (CDRH). DSMICA provides technical assistance on requests to aid small businesses in this area, and also assists in identifying ways manufacturers can avoid postmarket surveillance actions through the use of least burdensome practices. DSMICA maintains a toll-free telephone number and a “Facts-On-Demand” Fax back service for the convenience of 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

Notice was published in the Federal Register October 2, 2006(71 FR 57973) (Attachment 3) soliciting comments on the original information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d). No comments were received.

FDA meets with companies on an ongoing basis to discuss ways to perform least burdensome actions which will allow companies to avoid postmarket surveillance actions. All items brought up with companies will help determine which companies require postmarket surveillance. Each action is determined on a case by case basis. There are no hard and fast rules on the determination of a company's postmarket surveillance action. FDA evaluates each case, and does what makes sense to protect the health and safety of the public.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts 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 and the total cost estimate follows the table.

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	5	1	5	120	600
822.21	3	1	3	40	120
822.27	1	1	1	40	40
822.28	1	1	1	8	8
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.33	1	1	1	20	20
822.37	10	2	20	120	2,400
Total					3,348

[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
822.31	10	1	10	20	200
822.32	30	1	30	10	300
Total					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 expects to issue approximately 5 surveillance orders per year, covering approximately 3 device types. Each manufacturer 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 822.38). Based on its knowledge and experience with postmarket surveillance under SMDA, FDA estimates that it takes approximately 120 hours to prepare a postmarket surveillance plan for submission to the agency, for a total burden of 600 hours for preparing postmarket surveillance plans (5 plans x 120 hours per plan). FDA expects that, on a case-by-case basis, requests for additional information may be made from a manufacturer. As noted in Table 1, FDA anticipates that a small number of respondents will propose changes to their postmarket surveillance plans (21 CFR 822.21), request a waiver of a specific requirement of this regulation (21 CFR 822.29), or request exemption from the requirement to conduct postmarket surveillance of their device (21 CFR 822.30). FDA's

experience has shown that a few respondents will go out of business (21 CFR 822.27) or cease marketing the device subject to postmarket surveillance (21 CFR 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes (21 CFR 822.34). The burden captured in Table 1 for each of these responses is based on FDA experience to date.

Section 822.26 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

FDA expects 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, FDA has 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 FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Devices Act (SMDA). Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 10 manufacturers (3 - 4 added each year) and 30 investigators (three per surveillance plan). After three years, FDA 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 is no additional operating and maintenance cost or capital cost associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates that approximately 3 staff-years will be devoted to this activity annually, at a cost of $ 352,200, based on FY 2006 FTE of 1750 hours at $117,400.

15. Explanation for Program Changes or Adjustments

In the past three years, there have been fewer respondents to this collection of information due to FDA and industry resolving issues in other ways than initiating postmarket surveillance actions. When this collection was approved by OMB three years ago, FDA estimated that 5,778 combined reporting and recordkeeping hours were needed to complete the requirements of the collection. However, due to increased industry and FDA effort to consider additional methods to gather key postmarket information, the requirements of this collection have been reduced. Therefore, FDA now estimates that 3,848 total reporting and recordkeeping hours are needed for this collection, resulting in a savings of 1,930 hours.

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

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.

Attachment 1 -- 21 CFR Part 822
Attachment 2 – Section 522 of the FD& C Act
Attachment 3 – FR notice soliciting comments.