POSTMARKET SURVEILLANCE
(21 CFR 822)
0910-0449
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Collection Necessary

Abstract

The Food and Drug Administration (FDA) is requesting approval to continue information collection requirements in 21 CFR Part 822.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=822

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.
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm110307.htm

Reporting:

21 CFR 822.9 and 822.10

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 822.21

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

21 CFR 822.28

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

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

21 CFR 822.30

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

21 CFR 822.38

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

Recordkeeping:

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.

21 CFR 822.32

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

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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 of the respondents are private sector, which are business or other for-profit.

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.

100% of the 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, many 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, 21 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

As required by 21 CFR 822, manufacturers submit:

- PS reports on an annual or semi-annual basis
- 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

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

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Notice was published in the Federal Register 2/5/2010 (75 FR 6036) 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. http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0033

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 manufacturer'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 applications, 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 Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
822.9, 822.10	21	1	21	120	2520
822.21	5	1	5	40	200
822.28	5	1	5	8	40
822.29	1	1	1	40	40
822.30	1	1	1	40	40
822.38	40	1	40	40	1600
Total					4440

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

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Records	Total Hours
822.31	21	1	21	20	420
822.32	63	1	63	5	315
Total					735

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

Explanation of Reporting Burden Estimate

The burden captured in Table 1 for each of these responses is based on the data available in FDA's internal tracking system for 2009. There was not an internal tracking system prior to 2009.

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 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 21 manufacturers (3 - 4 added each year) and 63 investigators (3 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.

Please note that the recordkeeping burden was adjusted to reflect a reduction in the number of hours per record for the investigator (822.32) based on a reassessment. The number of hours per record was reduced from 10 to 5 and the total burden hours were reduced from 630 to 315. This resulted in a total burden hour reduction from 1050 to 735.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturer	4860	$40.00	$194,400
Clinical Study Manager	315	$45.00	$14,175
Total			$208,575

13. Estimates of Other Total Annual Cost 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 approximately 3 staff-years will be devoted to this activity annually, which based on FY 2009 FTE at $105,000 annual salary, will result in an annualized cost of $315,000,

15. Explanation for Program Changes or Adjustments

The adjustment in burden is due to an increase in postmarket surveillance orders received by FDA. Additionally, the use of a new internal tracking system has allowed the agency to be

more precise in its estimates. These factors led to an increase of 1328 overall total burden 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.