Postmarket Surveillance

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.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=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 a manufacturers to conduct postmarket surveillance of any device that meets the criteria set forth in the statute.

Reporting:

Postmarket surveillance (PS) submission (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.

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)
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.

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.

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 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. 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.

During the past three years, 131 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.

FDA offers the resources of the Center for Devices and Radiological Health's (CDRH) Division of Small Manufacturers, International and Consumer Assistance (DSMICA). CDRH established DSMICA as required by the 1976 Amendments to the FD&C Act. DSMICA'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 on identifying ways manufacturers can avoid postmarket surveillance actions through the use of least burdensome practices. The activities of DSMICA 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 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

   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 05/16/2013 (78 FR 28853). 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 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

    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)	131	1	131	120	15,720
Changes to PS plan after approval (822.21)	15	1	15	40	600
Changes to PS plan for a device that is no longer marketed (822.28)	80	1	80	8	640
Waiver (822.29)	1	1	1	40	40
Exemption request (822.30)	16	1	16	40	640
Periodic reports (822.38)	131	3	393	40	15,720
Total					33,360

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)	131	1	131	20	2,620
Investigator records (822.32)	393	1	393	5	1,965
Total					4,585

Explanation of Reporting Burden Estimate:
The burden captured in Table 1 is based on the data available in 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.

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 2012 National Occupational Employment and Wage

Estimates United States (http://www.bls.gov/oes/current/oes_nat.htm) for the following occupations: Operations Specialties Managers ($53.54/hour; occupation code 11-3000), Administrative Services Managers ($42.63/hour; occupation code 11-3011), and General and Operations Managers ($55.22/hour; occupation code 11-1021).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Respondent	37,945	$50.46	$1,914,705

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. An average full time equivalent (FTE) employee is projected to cost FDA/CDRH $209,632,* which consists of the employee's salary and any overhead which accompanies that employee. The burden imposed upon the government for this information collection is, therefore, approximately $628,896.

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

The number of submitters for all the ICs, except Waivers under section 822.29, has increased since the last information collection approval. In one case, both the number of submitters and the number of times per year that they send the information increased (Periodic reports (822.32). This adjustment in burden is based on the data available in FDA's internal tracking system.

A detailed explanation on the adjustments follows:

- "Postmarket surveillance submission (822.9 and 822.10)" respondents increased by 110;
- "Changes to PS plan after approval (822.21)" respondents increased by 10,
- "Changes to PS plan for a device that is no longer marketed (822.28)" respondents increased by 75;
- "Exemption request (822.30)" respondents increased by 15;
- "Periodic reports (822.38)" respondents increased by 91, annual frequency per response increased by 2;
- "Manufacturer records (822.31)" recordkeepers increased by 110; and

- "Investigator records (822.32)" recordkeepers increased by 330.

These adjustments have caused an increase of 28,920 reporting burden hours and 3,850 recordkeeping hours. The new reporting burden is 33,360 (28,920+4,440) and recordkeeping burden 4,585 (735+3,850). The total estimated burden for this collection is now 37,945.

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 is not seeking approval not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.