MEDICAL DEVICES; THIRD-PARTY REVIEW UNDER FDAMA
OMB No. 0910-0375
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary.

Abstract

Section 210 of FDAMA established section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C act) (21 U.S.C. 360m), http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm110312.htm directing FDA to accredit persons in the private sector to review certain premarket notifications [510(k)s]. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) of the act (21 U.S.C. 360) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

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

2. Purpose and Use of the Information Collection

The respondents for this information collection are private sector, for-profit institutions.

The purpose of the program is: (1) to provide manufacturers of eligible devices with an alternative review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, individuals may apply for accreditation as third-party reviewers and, if accredited, must submit reports of their reviews to FDA.

3. Use of Information Technology and Burden Reduction

FDA estimates that 50% of the respondents requesting accreditation will do so electronically. FDA further estimates that none of the respondents, or 0%, of the 510(k) reviews will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the collection of information required under the third-party review program. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Business or Other Small Entities

The number of respondents for this information collection who are small businesses is approximately 88%.
Participation in the third-party program is entirely voluntary. As such, there is potentially no impact on small businesses unless they elect to participate in the program.

FDA aids small business by providing guidance and information through the Division of Small Manufacturers International and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health (CDRH). DSMICA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free 800 telephone number, E-mail account and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

Both accreditation respondents and 510(k) reviews are submitted once under the information collection. Also, there is no established frequency for the information collection under the third-party review program, so consequences of collecting this information less frequently are minimal.

There are no legal obstacles to reduce the burden.

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

This regulation is consistent with principles in 5 CFR 1320.5.

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 September 22, 2010 (75 FR 57801). FDA received one comment, however it was not PRA related.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondents

Information regarding Accredited Third Parties, and review reports by Accredited Third Parties are available under the Freedom of Information Act and 21 CFR Part 20.

11. Justification for Sensitive Questions.

The information required in a premarket approval or premarket supplement application does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Annualized Burden Hours and Costs

12a. Annualized Hours Burden Estimate

The following is a summary of the estimated annual burden hours for participation in the voluntary program.

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

Estimated Annual Reporting Burden[1]

Section 523 of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Requests for Accreditation	1	1	1	24	24
510(k) reviews conducted by accredited 3rd parties	10	26	260	40	10,400
Totals					10,424

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

Estimated Annual Recordkeeping Burden[1]

Section 523 of the Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510(k) reviews	10	26	260	10	2,600

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

12.a.1. Reporting

a. **Requests for accreditation**: In the past three years, the agency has averaged receipt of 1 application for accreditation for third party review.

b. **510(k) reviews conducted by accredited third parties:** According to FDA's data in 2009, the agency has experienced that the number of 510(k)'s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

12.a.2. Recordkeeping

Third party reviewers are required to keep records of their review of each submission. According to FDA's in 2009, the agency anticipates approximately 260 submissions of 510(k)'s for third party review per year.

12b. Annualized Cost Burden Estimate

There are no costs imposed by this program, as it is a voluntary program intended to provide manufacturers with an alternative path of review. The cost of conducting reviews and submitting reports will be charged by accredited third-parties to manufacturers who choose to participate in the program, but such cost is not established by the program requirements.

An Accredited Person may assess a reasonable fee for their services. The fee for a 510(k) review is a matter to be determined by contract between the Accredited Person and the submitter. Although FDA is not aware of the average fee for 510(k) review conducted by an Accredited Person, we believe it to be close to the standard user fee imposed by the FDA for conducting a 510(k) review. For fiscal year 2011, the standard fee for a 510(k) review is $4,348.

13. Estimates of the Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Costs to the government are limited to the time required to review applications for accreditation, and submitted 510(k) review reports. The agency had determined that no additional costs of FTE's would be required to conduct such reviews.

Approximately 35 hours is required to complete a 510(k) review report at GS-14 salary cost of $51 dollars an hour. The total cost is $1,785.

15. Explanation for Program Changes or Adjustments

There has been a decrease of 4,040 burden hours and 76 annual responses since this collection's last approval by OMB in 2007. This adjustment is a result of a decrease in the number of annual reviews that each third party reviewer has processed.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

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

FDA is not seeking an exemption of display of effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.