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

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 210(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) added section 523 to the Federal Food, Drug, and Cosmetic Act (Attachment A). Section 523 authorizes FDA to accredit third party organizations to conduct the primary review of premarket notifications [510(k)s] for certain low and moderate risk devices.

Under this program, companies may apply for accreditation as a third-party reviewer of 510(k) premarket notifications required by the Food and Drug Administration (FDA). Accredited third-party reviewers will be able to perform 510(k) reviews for certain medical devices, and must submit reports of such reviews to FDA. Third-party review is elective and at the discretion of the manufacturer of the product. Accredited third parties must maintain records of their 510(k) reviews for a period of no less than 3 years.

2. Purpose and Use of the Information

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

This program allows alternative appropriate technology. Applications and reports can be electronically submitted if the format is compatible with FDAs technology.

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

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

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.

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 Agency

Notice has been published in the Federal Register on June 21, 2007 (72 FR 34258) soliciting comments on this 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.

In the past three years, FDA has not received any comments regarding this information collection.

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 Respondent

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 Hour Burden Including Annualized Hourly Costs

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 Responses	Hours per Response	Total Hours
Requests for Accreditation	1	1	1	24	24
510(k) reviews conducted by accredited 3rd parties	14	24	336	40	13,440
Totals					13,464

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

Estimated Annual Recordkeeping Burden[1]

Section 523 of the Act	No. of Record-keepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record-keeper	Total Hours
510(k) reviews	14	24	336	10	3,600

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

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 2007, the standard fee for a 510(k) review is $4,158.

The burden imposed by this information collection is as follows:

1. Reporting

a. **Requests for accreditation**: Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third party reviewers, of which the agency recognized 7. In the past three years, the agency has averaged receipt of 15 applications for recognition of third party review Accredited Persons. The agency has accredited 15 of the applicants to conduct third-party reviews.

b. **510(k) reviews conducted by accredited third parties:** In the 18 months under the Third Party Review Pilot Program, FDA received twenty-two 510(k)'s that requested and were eligible for review by third parties. The agency has experienced that the number of 510(k)'s submitted for third-party review since the last OMB approval in 2001 is approximately 210 annually, which is 14 annual reviews per each of the estimated 15 accredited reviewers.

2. Recordkeeping

Third party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 210 annual submissions of 510(k)'s for third party review.

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

No capital or operational expenses are expected as a result of this proposal.

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 net change of 2,604 estimated burden hours since this collection's last approval by OMB in 2004. Reporting burden has increased due to an increase in the number of annual reviews that each third party reviewer has processed. Recordkeeping has also increased by 1,500 hours due to increases in the number of reports filed by Accredited Persons.

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.