

SUPPORTING STATEMENT FOR
MEDICAL DEVICES; THIRD-PARTY REVIEW UNDER FDAMA

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Reporting

Requests for accreditation as third-party reviewer - 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).

510(k) reviews conducted by accredited third-parties - Under this program, 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.

Recordkeeping

Accredited third-parties must maintain records of their 510(k) reviews for a period of no less than 3 years.

On May 22, 1998, FDA issued a notice (Tab A) announcing implementation of third-party review under FDAMA and seeking emergency processing of a request for approval of the information collection requirements in the program. Also on May 22, 1998, FDA issued a notice of availability of a guidance document (Tab B) describing the third-party review program. The program is an expansion of the Center for Devices and Radiological Health's (CDRH) Third Party Review Pilot Program which was established August 1, 1996. 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.

2. By Whom and for What Purpose the Information is to be Used

Information from these information collection provisions will be used to implement section 210 of FDAMA requiring FDA to establish a third-party review program.

3. Consideration of Information Technology

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

4. Efforts to Identify Duplication and Similar Information Already Available

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. Small Businesses

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 Assistance (DSMA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMA 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 which firms may use to obtain regulatory compliance information.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles.

There is no established frequency for the information collection under the third-party review program.

7. Consistency with the Guidelines in 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5.

8. Consultation Outside the Agency

The third-party review program is an expansion of a third-party review pilot program established by CDRH on August 1, 1996. During the time the pilot program was in place, FDA received favorable feedback from industry.

In the **Federal Register** of May 22, 1998 (Tab), FDA invited interested persons to comment on the emergency notice until June 22, 1998. FDA received no comments in response to this notice.

In the Federal Register of August 4, 1998 (63 FR 41575), FDA invited interested persons to comment (Tab D). FDA once again received no comments in response to this notice.

9. Payments or Gifts to Respondents

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

10. Confidentiality of Information

Information regarding U.S. CABs, and review reports by E.C. CABs are available under the Freedom of Information Act and 21 CFR Part 20.

11. Sensitive Questions

The information collection does not include questions concerning sex, behavior, attitudes, religious beliefs, or private matters.

12. Estimates of Burden Hours and Explanation _____

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

ESTIMATED ANNUAL BURDEN FOR REPORTING

<i>ITEM</i>	<i>NUMBER OF RESPDTS</i>	<i>NUMBER RESPONSES PER RESPDT</i>	<i>TOTAL ANNUAL RESPONSES</i>	<i>HOURS/RESPDT</i>	<i>TOTAL HOURS</i>
Requests for accreditation	40	1	40	24	960
510(k) reviews conducted by accredited 3rd parties	35	4	140	40	5,600
					6,560

ESTIMATED ANNUAL RECORDKEEPING BURDEN

<i>ITEM</i>	<i>Number of Record-keepers</i>	<i>Annual Frequency per Record keeping</i>	<i>Total Annual Records</i>	<i>Hours/Record keeper</i>	<i>Total Hours</i>
510(k) reviews	35	4	140	10	1,400

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 the Accredited third-parties to manufacturers who choose to participate in the program, but such cost is not established by the program requirements.

13. Annual Costs to Respondents

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

14. Government Costs:

Costs to the government is 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.

15. Changes in Burden

This is a new information collection.

16. Statistical Reporting

No publication of information for statistical use is planned.

17. Exemption for Display of Effective Date

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

18. Exception to Certification Statement

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

List of Attachments:

Tab A - Notice of Implementation of third Party Review Program under FDAMA and Request for Emergency Processing of Information Collection

Tab B - Guidance Document for Implementation of Third Party Programs under FADAMA

Tab C - Federal Register Notice of August 4, 1998