Medical Devices; Third-Party Review Under FDAMA

0910-0375

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   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) submission for selected devices (21 U.S.C. 360). 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.
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 Improved Information Technology and Burden Reduction

   FDA estimates that 50% of the respondents requesting accreditation will do so electronically.

   Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144). FDA implemented eCopy requirements on January 1, 2013, with the issuance of the final eCopy guidance

(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf). The guidance describes how device companies must replace at least one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy program, as well as the technical standards for an eCopy, are described in the guidance. The eCopy requirements do not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR and, therefore, do not change the cost or hour burden. Therefore, FDA further estimates that approximately 100% of the respondents will use electronic means to fulfill the agency's requirement for 510(k) reviews.

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 Businesses 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 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

   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 07/08/2016 (81 FR 44627). We received no comments on the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents to this information collection.

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. Data will be kept private to the extent allowed by the law.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour 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:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	10	26	260	40	10,400
Total					10,424

Table 2.--Estimated Annual Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510(k) reviews	10	26	260	10	2,600

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, 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.

Recordkeeping:

Third party reviewers are required to keep records of their review of each submission. According to FDA's data, 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 2017, the standard fee for a 510(k) review is $4,690.

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

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 a GS-14, step 10 employee (in the area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA) salary cost of $67.83 dollars an hour, the total cost is $2,374.

15. Explanation for Program Changes or Adjustments

FDA is requesting an extension of the information collection approval. There are no program changes or adjustments.

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 from display of the effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.