513(g) Request for Information

0910-0705

SUPPORTING STATEMENT

**Terms of Clearance:** "In accordance with the terms of 5 CFR 1320, OMB approves this ICR for a period of three years. If FDA requests an extension of this approval, FDA should make significant progress in making an electronic submission available. If electronic submission is not available, the agency should submit a timeline for implementation and report on progress."

On December 12, 2012, FDA submitted a nonmaterial/non-substantive change request (83-C) for approval of a change from optional to required electronic submission of an electronic copy of the product approval submissions covered in this, among several other, ICRs. 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's implementing guidance describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. OMB approved the change request on December 19, 2012. We believe this change satisfies the terms of clearance for this ICR.

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

   Section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the act) (21 U.S.C. 360c, et seq.) provides for the classification of devices intended for human use. Under section 513(a), devices are classified by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness into class I (general controls), class II (special controls), or class III (premarket approval). Section 513(g) provides a means of obtaining information from FDA regarding the classification and regulatory requirements that may be applicable to a particular device; specifically, that within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of this act applicable to the device.

   While FDA has developed form 3601, "Medical Device User Fee Cover Sheet," to assist individuals seeking information under 513(g), the agency is now issuing a guidance entitled "FDA and Industry Procedures for section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act" to assist individuals in preparing the supplemental information necessary to process the requests.
2. Purpose and Use of the Information Collection

FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) will use the information submitted in a 513(g) request to provide information regarding classification information and/or regulator requirements for a single product. Parties seeking information for multiple products must submit separate 513(g) requests for each product.

FDA believes that the majority of respondents will be private, for-profit businesses, however individuals, as well as state, local, and tribal governments may also submit 513(g) requests.

3. Use of Improved Information Technology and Burden Reduction

Although FDA Form 3601 may be completed electronically (approved under OMB Control No. 0910-0511), it must accompany the supplemental material described in the guidance for this information collection in order for FDA to satisfy requests for information under section 513(g). In addition, the agency requires that respondents submit two copies of each 513(g) request, including the Form 3601. Because more than one agency component may have information responsive to a 513(g) request, FDA believes that the submission of two copies will expedite its response.

On December 12, 2012, FDA submitted a nonmaterial/non-substantive change request (83-C) for approval of a change from optional to required electronic submission of an electronic copy of the product approval submissions covered in this, among several other, ICRs. 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's implementing guidance describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. OMB approved the change request on December 19, 2012. FDA expects, therefore, 100% of respondents will submit the information in electronic and written form.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. The information is not available from any other source. The agency will collect two copies of each 513(g) request for information, which are to be submitted in conjunction with Form 3601, and submitted once for each product inquiry.

5. Impact on Small Businesses or Other Small Entities

Respondents to this collection of information are mostly device manufacturers, however, anyone may submit a 513(g) Request for Information. Using the guidelines set by the Small Business Administration on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments are considered small businesses.

To offset the need for a request under 513(g), FDA maintains information publically accessible on the Internet, including a product classification database, a 510(k) database,

a list of class I and class II devices exempt from 510(k) requirements, and access to CDRH's Division of Industry and Consumer Education. In addition, FDA's website provides access to medical device guidance documents and information regarding particular types of devices regulated by CBER.

6. Consequences of Collecting the Information Less Frequently

   Respondents do not respond to the information collection on a fixed schedule or with a specific frequency, but rather, submit two copies of the information with each request, including Form 3601 (i.e., occasionally). If FDA is not able to collect the information and associated user fees, the agency cannot fulfill its obligation under section 513(g) of the act.

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 07/22/2014 (79 FR 42517). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift has been or will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and the agency's published regulations of "Public Information," under 21 CFR Part 20, which prohibit FDA from releasing to the public any information that cannot be disclosed. Such information is deleted from any information released by FDA under FOIA and FDA regulations.

11. Justification for Sensitive Questions

    This information collection does not include questions that are of a sensitive nature, such as, 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

    The estimated annual burden for this information collection is 1,368 hours.

Table 1.--Estimated Annual Reporting Burden

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| CDRH 513(g) requests | 114 | 1 | 114 | 12 | 1,368 |
| CBER 513(g) requests | 4 | 1 | 4 | 12 | 48 |
| Total | | | | | 1,416 |

Respondents to this collection of information are mostly device manufacturers, however, anyone may submit a 513(g) Request for Information. The total number of annual responses is based on the average number of 513(g) requests received each year by the agency.

12b. Annualized Cost Burden Estimate

The cost to respondents is based on the average salary for a regulatory affairs specialist ($75.00) times the total number of hours estimated to prepare the supplemental information in 513(g) requests.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Regulatory Affairs Specialist | 1,416 | $75.00 | $106,200 |

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

The estimated cost to the Federal Government is $212,400 annually, and is based on multiplying the average salary for a GS-13 reviewer ($50.00) times the number of annual submissions and the hours of review:

| **Activity** | **No. of Responses** | **Hours per Response** | **Cost per Hour** | **Total Cost** |
|---|---|---|---|---|
| 513(g) Request; Supplemental Information review | 118 | 36 | $50.00 | $212,400 |

15. Explanation for Program Changes or Adjustments

The total burden hours have increased by 48 hours. This adjustment is due to a slight increase in the number of respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.