U.S. Food and Drug Administration
513(g) Request for Information
OMB Control No. 0910-0705

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: None.

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA or we) program and accompanying guidance. Section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the act) (21 U.S.C. 360c) 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.

   To assist respondents with the information collections related to section 513 of the act, we issued a guidance document entitled "FDA and Industry Procedures for section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act," on April 6, 2012. The guidance is intended to assist individuals in preparing their requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the act. The request should contain a cover letter, a description of the device, a description of what the device is to be used for, and any proposed labeling or promotional material of a similar, legally, marketed device, if available. Information is submitted using Form FDA 3601, "Medical Device User Fee Cover Sheet" (approved under OMB Control No. 0910-0511), to provide, among other things, the written statement of classification under 513(g).

   We therefore request extension of OMB approval for the information collection provisions under 513(g) of the act, as well as recommendations in the accompanying guidance document as referenced above.

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) uses information submitted in a 513(g) request to provide information regarding classification information and/or regulatory requirements for a single product. Any person seeking information for multiple products must submit separate 513(g) requests for each product.

Respondents to the information collection include 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

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), requires the submission of eCopies upon the issuance of final guidance. The guidance entitled, "*eCopy Program for Medical Device Submissions; Guidance for Industry and FDA Staff*," provides, among other things, the standards for a valid eCopy under section 745A(b)(2)(A) of the act for different kinds of medical device submissions. As explained in the guidance, the inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. The guidance describes how device companies should replace one paper copy of a device application with an eCopy. FDA expects, therefore, 100% of respondents will submit the information in electronic and written form; however, submission of an eCopy is voluntary for 513(g) requests.

The agency requires that respondents submit two copies of each 513(g) request. Because more than one agency component may have information responsive to a 513(g) request, we believe submitting two copies will expedite our response.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small businesses or small entities. To offset the need for a request under 513(g), FDA maintains information publicly 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

The information collection schedule is consistent with statutory requirements of the act and applicable regulations

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

There are no special circumstances for this collection of information. The guidance documents "FDA and Industry Procedures for section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act 513(g)" and "eCopy Program for Medical Device Submissions; Guidance for Industry and FDA Staff", both state that two copies of 513(g) requests are required. However, under "eCopy Program for Medical

Device Submissions; Guidance for Industry and FDA Staff", the requester may voluntarily choose to submit one eCopy.

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 November 21, 2017 (82 FR 55381). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    The confidentiality of information received by FDA is consistent with and limited to 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

    12a. Annualized Hour Burden Estimate

    The estimated annual burden for this information collection is 1,416 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

The total number of annual responses is based on the average number of 513(g) requests received each year by CDRH and CBER respectively.

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

    Using 2017 OPM salary and wage data, we calculate a cost of $212,400 to the Federal Government. This figure assumes the average salary for a GS-13 reviewer ($50.00) and is multiplied by the annual hourly burden as derived from the number of annual submissions:

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 information collection is unchanged from the currently approved burden.

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 will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.