

**513(g) Request for Information
0910-[NEW]
SUPPORTING STATEMENT**

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.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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

FDA expects, therefore, 100% of respondents will submit the information in written form.

CDRH hopes to move toward electronic submissions for a variety of applications (either as an option or only means of submission). Depending on funding and logistics, we are 3-5 years away from that happening

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information, nor is the information 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 and Other Entities

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 Small Manufacturers, International, and Consumer Assistance. 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 Collection 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. 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 the collection of information requirements.

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 on April 29, 2010 (75 FR 22599) soliciting comments on the information collection for 513(g) requests. No comments were posted to the docket.

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

Questions of a sensitive nature are not applicable to this information collection.

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 Burden¹

FD&C Act 513(g)	No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
CDRH	110	1	110	12	1,320
CBER	4	1	4	12	48
Total					1,368

¹. There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers, however, any one 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 number of hours necessary to prepare the supplemental information in a 513(g) request.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
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Regulatory Affairs Specialist	12	\$75.00	\$900.00
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13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital and start-up, or operation, maintenance and purchase costs associated with this information collection.

14. Annualized Costs to the Federal Government

The estimated cost to the Federal Government is \$176,472.00 annually, and is based on multiplying the average salary for a GS-13 reviewer (\$43.00) 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	114	36	\$43.00	\$176,472.00

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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 Item 19 of OMB Form 83-I.