OMB INFORMATION COLLECTION
SUPPORTING STATEMENT

Medical Device User Fee Cover Sheet - Form FDA 3601
0910-0511

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval for the collection of information for the Form FDA 3601, Medical Device User Fee Cover Sheet (Tab A).

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), www.fda.gov/cdrh/mdufma/mdufma 2002.html authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601 is the Medical Device User Fee Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

2. Purpose and Use of the Information

The User Fee Cover Sheet is designed to be included with each medical device application subject to fees under MDUFMA submitted to FDA for review. The information collected will be used by the FDA's Center for Device and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of an application or supplement. The form provides a cross-reference of the fee submitted for an application with the actual application utilizing a unique number tracking system. It also identifies pertinent statutory provisions under which the application may qualify for a reduced fee or be excluded from the requirement for a fee.

MDUFMA requires the submission of the user fees concurrently with applications. If the required fees are not submitted, the review of the application will not begin. The User Fee Cover Sheet provides the information necessary to either initiate or defer the application review.

3. Use of Information Technology and Burden Reduction

The MDUFMA User Fee Cover Sheet form is now available on FDA's website at http://www.fda.gov/oc/mdufma/coversheet.html. The new cover sheet system asks questions electronically that answer the fields in the form after the customers login the system. The form is designed to obtain the minimum needed information for FDA to determine whether a fee is required for the review of an application, assess the amount of fee required, and account for and track user fees based on the answers provided by the customers online.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. The required information is not available from any other sources.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CDRH's Division of Small Manufacturer's, International and Consumer Assistance and CBER's Office of Communication, Training, and Manufacturer's Assistance provides assistance to small businesses subject to regulatory requirements.

MDUFMA includes a waiver provision for small businesses. Businesses that have been granted a waiver of fees under this provision can note their exclusion from the fee requirement by utilizing this User Fee Cover Sheet.

6. Consequences of Collecting the Information Less Frequently

This form is not used for the periodic collection of information. Rather, the form is to be used once for each specific application or supplement at the time of submission. Its intent is to provide specific information to allow FDA to determine that the correct fee has been paid to allow prompt acceptance and initiation of the review of medical device applications and supplements. There can be no less frequent information collection than one request per application without the consequence of potential delay of acceptance of applications for which information necessary to process them is not provided.

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 Agency

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of June 29, 2006 (71 FR 37082). FDA received one comment and provided the following response:

.: The current layout of the online form is to ensure information and questions presented on the website are easy to read for all users. When this system was constructed, the Food and Drug Administration was limited to the format and the layout of questions and answers. FDA took an already approved form and created an interactive system that determines the payments of requested applications based on the answers to the questions. The questions are sequential. After completing the first question, the system decides and chooses the next question for the customers. This **Federal Register** notice renews the current construction. Careful consideration during the next review will be given and FDA will certainly consider the commenters suggestion of saving screen refresh time.

As noted above, FDA will be glad to take under consideration, the commenters template and the ability to download the form, when the next update or review is initiated. You can, however, retrieve an existing coversheet by logging into the system, and clicking on the name of the coversheet. The retrieved form is a photo shot html format. Thus, no changes can be made directly onto the form. To print the coversheet, please select Print Cover Sheet on the bottom of the form. Currently, the printed coversheet contains all information on one page. Again, FDA will be glad to consider this request during the next review. The current coversheet is designed to contain all information on one page. By creating more room on the left margin, the form may extend to two pages.
Having instructions 1 through 6 on the coversheet seems redundant. However, at the time, when creating the interactive system, FDA took into consideration that once a coversheet is completed and ready to mail, all information would be displayed on the same page. Instructions 1 through 6 are very important information for all customers to follow in order to expedite the application review process. The instructions printed on the coversheet provide easy access for all customers to learn about them, especially for new users. FDA will continue to use the current form. For other questions regarding submitted coversheets, please contact the User Fee Hotline at 301-827-9539, or email to User Fee Financial Support Team at userfees@fda.gov.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided 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 Hour Burden Including Annualized Hourly Costs

The estimated annual burden for this information collection is 1,380 hours.

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3601	4,600	1	4,600	0.30	1,380

Respondents to this collection of information are device manufacturers. According to FDA database system, there are an estimated 4,600 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any coversheet submissions in a given year and some may have multiple coversheet submissions. The total number of annual responses is based on the number of coversheet submissions received by FDA in fiscal year 2005. CDRH received 4,436 annual responses that included the followings: 43 premarket approval applications, 4,071 premarket notifications, 22 modular premarket applications, 1 product development protocol, 1 premarket report, 15 panel track supplements, 174 real-time supplements, and 109 180-day supplements. CBER received 106 annual responses that included the followings: 2 premarket approval applications, 16 biologics license applications, 84 premarket notifications, 1 modular premarket application, 2 180-day supplements, and 1 real-time supplement. The number of received annual responses in FY 2005 included the coversheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various coversheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1,380	$40	$55,200

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of $40 per hour, who is responsible for filling out, signing, and submitting the application. This salary estimate includes benefits but no overhead costs.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

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 annualized cost to the Federal Government is $39,434.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3601	4,600	0.75	$20	$92,000

The estimated time for review, data entry, and tracking is 45 minutes. The information from the form will be extracted by both program and administrative support personnel (GS-4 through GS-7) with an average salary (including benefits but not overhead) of $20 an hour.

15. Explanation of Program Changes or Adjustments

There was a slight decrease from the previous burden estimate, i.e. from 1500 hours to 1380 hrs due to the Center reevaluating the data for this collection of information.

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. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.