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

Abstract
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), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), 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, the "Medical Device User Fee Cover Sheet", 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. The link below takes you to the coversheet instructions and a link to create a coversheet.

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

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. The

consequence of not providing all necessary information is that the submission in question cannot be reviewed.

The majority of the respondents are private sector businesses, specifically medical device manufacturers.

3. Use of Information Technology and Burden Reduction

The MDUFMA User Fee Cover Sheet form is now available on FDA's website at https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp. 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.

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

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

In Fiscal Year 2008 FDA received 1,012 coversheets from companies that qualified as a small business. 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 that grants discounted user fee rates. Businesses that have been granted a waiver of fees under this provision can obtain a one-time waiver of the fee for their first (ever) premarket application (premarket approval application, biologics license application, product development protocol, or premarket report).

6. Consequences of Collecting the Information Less Frequently

Respondents do not respond to the data collection on fixed schedule or at a specific frequency. Each time an application or supplement for a medical device is submitted to FDA, the respondent completes the form and submits the required information.

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 the Agency

No comments have been received in response to the Federal Register Notice. Respondents have until December 14, 2009 to submit their responses. There are no known issues at present. This project does not relate to any other Federal program. The FDA has held quarterly meetings with the medical device industry to discuss the MDUFMA user fee program since its inception in 2002. There are no pending issues to be resolved.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of 10/15/2009 (74 FR 52965). No comments have been received in response to the Federal Register Notice

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

12a. Estimates of Annualized Burden Hours and Costs

The estimated annual burden for this information collection is 1,558 hours.

TABLE 1.—Estimated Annual Reporting Burden1

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Medical Device Manufacturers	3601	5,192	1	5,192	18/60	1,558

[1]There are no capital costs and operating and maintenance costs for this collection of information.

Respondents to this collection of information are device manufacturers. According to FDA database system, there are an estimated 5,192 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 2008. CDRH received approximately 5,095 annual responses that included the following submissions: 16 premarket approval applications (PMA, PDP, PMR, BLA), 3,625 premarket notifications, 8 modular premarket applications, 9 panel track supplements, 201 real-time supplements, 173 180-day supplements, 633 30-Day Notices, 93 513(g) Requests, and 337 Annual Fees for Periodic Reporting. CBER received approximately 97 annual responses that included the following submissions: 2 premarket approval applications (PMA, PDP, PMR, BLA), 1 BLA Efficacy Supplement, 50 premarket notifications, 3 180-day supplements, 2 real-time supplements, 20 30-Day Notices, 3 513(g) Requests, and 16 Annual Fees for Periodic Reporting. The number of received annual responses in FY 2008 included the cover sheets 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 cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

12b. Cost to Respondents

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.

Type of Respondent	Total burden hours	Hourly Wage Rate	Total Respondent Cost
Medical Device Manufacturers	1,5580	$40	$62,320

This estimate reflects the estimated annual cost for the next 3 years.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers/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 annualized cost to the Federal Government is $77,880.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3601	5,192	45/60	$20	$77,880

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 an increase in burden hours from 1,380 in 2006 to 1,558 in 2008. This is a direct result of the increased number of responses received. The amount of time on average to complete a coversheet has not changed in that time in that time period.

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.