Medical Device User Fee Cover Sheet—Form FDA 3601

0910-0511
SUPPORTING STATEMENT

Terms of Clearance: none.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   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. Form FDA 3601 and instructions are available online for registered users. A pdf of the form has been attached with this ICR.

2. Purpose and Use of the Information Collection

   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 Improved 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

FDA receives approximately 1,250 coversheets annually 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 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 October 21, 2015 (80 FR 63793). No comments were received.

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

    Data will be kept private to the fullest extent allowed by law. The Freedom of Information Act (FOIA) and the agency's regulations regarding "Public Information" under 21 CFR Part 20 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

    The 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

    Respondents to this collection of information are medical device manufacturers. According to FDA's database system, manufacturers of products subject to MDUFMA submit an average of 5,214 applications annually. However, not all manufacturers will have any cover sheet submissions in a given year and some may have multiple cover sheet submissions. 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 (18 minutes).

Table 1.--Estimated Annual Reporting Burden					
FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3601	5,214	1	5,214	0.30	1,564

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate is based on the estimated hourly wage rate for a Regulatory Affairs Professional, $61* per hour, who is responsible for filling out, signing, and submitting the application. FDA believes that the total estimated reporting burden cost will be $95,404, which is the total number of estimated annual burden hours (1,564) multiplied by the wage rate of $61 per hour.

**The estimated wage rate for a Regulatory Affairs Professional was based on The Regulatory Affairs Professional Society (RAPS) overall base annual compensation of $126,163 for a U.S. regulatory affairs professional (http://www.raps.org/news-trends/scope-of-practice/2014/). The hourly wage rate of $61 assumes a 40-hour work week and is rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	1,564	$61	$95,404

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 annualized cost to the Federal Government is $91,232. 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 of $23.33 per hour (based on Office of Personnel Management FY 2016 Salary Table 2012-DCB; https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx).

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3601	5,214	.75	$23.33	$91,232

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to the estimated hourly burden. There was an adjusted decrease of $141,624 to the estimated cost burden. The adjustment was made to correct an error in the calculation of the previous estimate which erroneously multiplied the respondent's wage rate by the number of respondents (5,214), rather than the estimated burden hours (1,564). Additionally, we have updated the wage rate from $45.46 to $61 per hour.

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 exemption from displaying the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.