

U.S. Food and Drug Administration
Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet —Form FDA
3601 and Form 3601(a)

OMB Control Number 0910-0511

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, us or we) medical device and device facility user fee program. 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 information collection request (ICR).

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration (Title 21 CFR Part 807). (Medical device establishment registration and listing is covered under OMB # 0910-0625). All establishments required to register must pay a user fee. Form FDA 3601(a), the “Device Facility User Fee Cover Sheet,” is designed to collect payments for the annual establishment registration fee for medical device establishments. Form FDA 3601(a) and instructions are available online for registered users. A pdf of the form has been attached with this ICR.

We therefore request OMB approval for the information collection provisions associated with the medical device and device facility user fee program and forms (Forms FDA 3601 and FDA 3601(a)) as discussed in this supporting statement.

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.

The Device Facility User Fee Cover Sheet is designed to collect payments for the annual establishment registration fee for medical device establishments.

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 available on FDA's website (https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?ref=https%3A%2F%2Fuserfees.fda.gov%2FOA_HTML%2FmdufmaCScdCfgItemsPopup.jsp%3Fordnum%3D6097306&sitex=10459:51717:US&sitex=10459:51717:US).

The 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.

The Device Facility User Fee Cover Sheet is available on FDA's website (https://userfees.fda.gov/OA_HTML/furls.jsp).

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

Approximately 25 percent of the information is from companies that qualified as a small business. 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 Industry and Consumer Education and CBER's Division of Manufacturer's Assistance and Training 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) (see OMB control number 0910-0508).

Waivers for small businesses are not applicable for 3601(a).

6. Consequences of Collecting the Information Less Frequently

Respondents do not respond to the data collection on Form 3601 on a 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 forms 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.

Form 3601(a) is collected on an annual basis because the fee is required annually.

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 June 12, 2020 (85 FR 35939). We received two comments in response to the notice. Only one comment was directly related to the notice. The comment referenced a reduced small business fee.

FDA's response to the comment is that the establishment registration fee is not eligible for a reduced small business fee. This can be found on our website at:

<https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3601 (Medical Device User Fee Cover Sheet) and Form FDA 3601(a) (Device Facility User Fee Cover Sheet) is employer identification number, payment identification number, name, email address, telephone number, and fax telephone number. Information collected via Form 3601 and 3601(a) is maintained in a Privacy Act system of records as described in HHS/FDA System of Records Notice (SORN) 09-10-0021 for FDA's User Fee System. Individuals completing Form 3601 and 3601(a) will complete it via the webpage where a notice is displayed. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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

12a. 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 6,182 applications annually and submit an average of 24,086 for Device Facility User Fee applications. 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). The total hours are rounded to the nearest whole number.

¹Numbers have been

Table 1.--Estimated Annual Reporting Burden¹

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3601 (Medical Device User Fee Cover Sheet)	6,182	1	6,182	0.30 (18 minutes)	1,855
3601(a) (Device Facility User Fee Cover Sheet)	24,086	1	24,086	0.17 (10 minutes)	4,095
Total			30,268		5,950

rounded.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents is \$702,100. We updated the annual cost burden estimate based on the wage rate for a Lawyer* (\$118), multiplied by the total estimated burden hours (5,950).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Attorney	5,950	\$118.00	\$702,100

* The estimated wage rate for a Lawyer is based on The Bureau of Labor Statistics (BLS) hourly wage rate of \$59 for a lawyer (<https://www.bls.gov/ooh/legal/lawyers.htm>, accessed 3-19-21). The hourly wage rate of \$118 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

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

We estimate the annualized cost to the Federal government is \$5,766,054. A full-time equivalent position (FTE) is estimated to cost FDA/CDRH \$263,326* annually, which consists of the employee's salary and any overhead which accompanies that employee. Assuming a 40-hour work week, that equals approximately \$127 per hour (rounded). FDA personnel spend approximately 1.5 hours for review, data entry, and tracking of forms 3601 and 3601(a) for 30,268 responses annually (1.5 hours x 30,268 responses = 45,402 burden hours). Therefore, \$5,766,054 is the annualized cost to the Federal government (45,402 burden hours x \$127=\$5,766,054).

*Based on the [FY 2020 FDA Budget Request – Executive Summary – All Table](#)

Activity	Total Burden Hours	Hourly Wage Rate	Total FDA Costs
Review, Data Entry, and Tracking of Forms 3601 and 3601(a)	45,402	\$127	\$5,766,054

15. Explanation for Program Changes or Adjustments

This information collection reflects changes and adjustments. By revising the collection to include Form FDA 3601(a), Device Facility User Fee Cover Sheet, and adjustment to the number of respondents for Form FDA 3601, there is an increase of 4,036 hours and a corresponding increase of 23,889 responses.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to tabulate or publish 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.