

United States Food and Drug Administration

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form 3601a

OMB Control Number 0910-0511--Revision

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

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 programs and guidance.

The Federal Food, Drug, and Cosmetic Act (the FD&C 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. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and FDA's Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

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 (21 CFR part 807, subparts A through D). (The information collection for medical device establishment registration and listing is approved under OMB control number 0910-0625.) All establishments required to register must pay a user fee. Form FDA 3601a, the "Device Facility User Fee Cover Sheet," is

designed to collect payments for the annual establishment registration fee for medical device establishments.

Under section 704(g) of the FD&C Act (21 U.S.C. 374(g)), FDA may accredit persons to inspect qualified manufacturers of class II and class III devices. An eligible establishment is permitted to select any FDA-accredited person to conduct an inspection in lieu of an FDA inspection, but the eligible establishment must submit notice to FDA for selection approval (see 21 U.S.C. 374(g)(1) and 374(g)(6)(B)). Referred to as the “Accredited Persons Inspection Program,” FDA publishes a complete list of accredited persons and the activities for which they are accredited on our website at [Third Party Device Inspection](#), along with additional information about the program.

The guidance document entitled, “FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act” (December 2019; updated August 23, 2024¹) provides FDA’s recommendations regarding provision of user fees for 513(g) requests for information under section 738(a)(2)(A)(ix) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(ix)). Instructions for submission and specific content elements are discussed in the guidance document in sections IV and V, respectively.

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)), the “Accredited Persons Inspection Program,” and the guidance document, “FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act,” as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The MDUFMA 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 CDRH and 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

¹ The August 23, 2024, update is a “Level 2 guidance document” as defined in FDA’s Good Guidance Practice regulations (see 21 CFR 10.115). Level 2 guidance documents set forth existing practices or minor changes in interpretation or policy.

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

FDA also collects user fees for the review of certain premarket submissions received including requests for information under section 513(g) of the FD&C Act (“513(g) request”). The additional funds obtained from user fees enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process.

Under the third-party inspection program FDA accredits persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices. The owner or operator of such an establishment that is eligible may select an Accredited Person, from FDA’s list to conduct such inspections. To be eligible for inspection by an Accredited Person, a device establishment must submit notice to the FDA to inform of the intent for the owner or operator to use an Accredited Person to conduct inspections of the establishment (“Notification of the intent to use an Accredited Person”). A person may submit a request to become an Accredited Person (“Request for accreditation”) by emailing [CDRH Accredited Persons Inspection@fda.hhs.gov](mailto:CDRH_Accredited_Persons_Inspection@fda.hhs.gov). Information can be found on FDA’s website ([Inspection by Accredited Persons Program | FDA](#)).

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

The cover sheet system asks questions electronically that automatically complete the fields on the form. 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 information provided by the customers online.

Manufacturers intending to be inspected by an Accredited Person under the third-party inspection program may submit notice (“Notification of the intent to use an Accredited Person”) to FDA electronically at [CDRH Accredited Persons Inspection@fda.hhs.gov](mailto:CDRH_Accredited_Persons_Inspection@fda.hhs.gov) to determine eligibility. A person may request to become an Accredited Person (“Request for accreditation”) by emailing [CDRH Accredited Persons Inspection@fda.hhs.gov](mailto:CDRH_Accredited_Persons_Inspection@fda.hhs.gov).

Respondents may elect to prepare their 513(g) request for information using CDRH's eSTAR voluntary guided submission preparation tool, which was developed to improve submission consistency and enhance efficiency in the review process.

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 collected is from small businesses. 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 to form FDA 3601a.

6. Consequences of Collecting the Information Less Frequently

Each time an application or supplement for a medical device is submitted to FDA, the respondent completes the form and submits the required information. Therefore, respondents do not respond to the data collection on form FDA 3601 on a fixed schedule or at a specific frequency.

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.

Manufacturers infrequently request eligibility to be inspected by an Accredited Person under the third-party inspection program.

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 FDA 3601a 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 February 29, 2024 (89 FR 14890). We received no comments in response to the notice.

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 3601a (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 3601a 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 3601a 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. The data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FDA Form or Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
User Fee Cover Sheet					
Form FDA 3601 (Medical Device User Fee Cover Sheet)	6,182	1	6,182	0.30 (18 minutes)	1,855
Form FDA 3601a (Device Facility User Fee Cover Sheet)	24,086	1	24,086	0.17 (10 minutes)	4,095
Subtotal			30,268		5,950
Inspection by Accredited Persons Program Under Section 704 of the FD&C Act					
Request for accreditation	1	1	1	80	80
Notification of the intent to use an Accredited Person	10	1	10	15	150
Subtotal			11		230
Request for Information Under Section 513(g) of the FD&C Act					
Sections IV and V of Guidance; CDRH 513(g) requests	114	1	114	12	1,368
Sections IV and V of Guidance; CBER 513(g) requests	4	1	4	12	48
Subtotal			118		1,416
Total					7,596

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

User Fee Cover Sheet

According to FDA's database system, manufacturers of products subject to MDUFMA submit an average of 6,182 applications and an average of 24,086 Device Facility User Fee 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 for form FDA 3601; 10 minutes for form FDA 3601a). The total hours are rounded to the nearest whole number.

Inspection by Accredited Persons Program Under Section 704 of the FD&C Act

Section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements a person must meet to be accredited to conduct inspections (an Accredited Person). A person may request to become an Accredited Person ("Request for accreditation") by emailing CDRH_Accredited_Persons_Inspection@fda.hhs.gov. The burden estimate for requests for accreditation is based on the number of applications we've received. Once an organization is accredited, it will not be required to reapply.

The AP Program permits eligible manufacturers to use Accredited Persons to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person. A device establishment is eligible for inspection by Accredited Persons if the establishment meets certain conditions of section 704(g)(6) of the FD&C Act, including that they provide notice of their intention to use an Accredited Person to conduct inspections of the establishment (“Notification of the intent to use an Accredited Person”).

We estimate there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on informal communications with industry, approximately 10 of these manufacturers may submit a notification of the intent to use an Accredited Person in any given year.

Request for Information Under Section 513(g) of the FD&C Act

Instructions for submission and specific content elements of 513(g) requests for information are discussed in the guidance document in sections IV and V, respectively. Respondents may elect to prepare their 513(g) request for information using CDRH’s eSTAR voluntary guided submission preparation tool, which was developed to improve submission consistency and enhance efficiency in the review process. The total number of annual responses is based on the average number of 513(g) requests received each year by CDRH and CBER respectively.

12b. Annualized Cost Burden Estimate

To estimate costs to respondents, we assume a wage rate for the labor category “Lawyers”* and doubled this figure to account for benefits and overhead (\$84.84 x 2=\$169.68). We then multiplied this wage rate by the estimated annual burden hours to calculate a total annualized cost burden of \$1,288,889 (rounded) (\$169.68 x 7,596 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (occupation code 23-1011) [May 2023 National Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/may2023.pdf).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	7,596	\$169.68	\$1,288,889

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

FDA estimates that approximately 24 full time equivalent (FTE) positions are needed for the administration of the information collection. Based on an internal cost model, we

assume a fully-loaded cost of \$348,722 per position (rounded). We calculate the annual Federal cost to be \$8,369,328.

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustments. In our March 2023 change request submission, we erroneously excluded the information collection entitled, “Notification of the intent to use an Accredited Person”. We have included the information collection activity in this renewal. The information collection, therefore, reflects a cumulative increase in burden by 10 annual responses and 150 burden hours. Also in the change request, we moved the 513(g) guidance to this ICR. We subsequently, on August 23, 2024, issued technical/Level 2 updates² to the guidance to reflect that 513(g) requests can be submitted using CDRH’s eSTAR voluntary guided submission preparation tool (noted above in section 3 of this supporting statement, and as noted in the approved March 2023 change request). We have provided the current guidance document, “FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act” with this request for approval.

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

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date. FDA will display the OMB expiration date as required by 5 CFR 1320.5 on forms.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

² See FDA’s Good Guidance Practice regulations regarding “Level 2 guidance document” (21 CFR 10.115(c)(2) and (g)(4)).