

United States Food and Drug Administration

MEDICAL DEVICE USER FEE SMALL BUSINESS QUALIFICATION AND
CERTIFICATION

OMB Control No. 0910-0508 – REVISION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), most recently reauthorized in 2022 from October 1, 2022, until September 30, 2027. To qualify as a “*small business*,” and therefore be eligible for reduced or waived fees, respondents submit information to FDA so we can determine whether the applicant is a small business. Sections 738(d)(2)(A) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a “*small business*” as an entity that reported \$100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm’s gross receipts or sales are no more than \$30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application (PMA), product development protocol (PDP), biological licensing application (BLA), or premarket report. The current user fees are shown at the [FDA MDUFA User Fees website \(https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa\)](https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa).

Forms FDA 3602 (“*MDUFA Small Business Certification Request for a Business Headquartered in the United States*”) and FDA 3602A (“*MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States*”) are submitted to FDA to demonstrate that an applicant qualifies as a “*MDUFA small business*,” and are submitted to FDA via the CDRH Customer Collaboration Portal (CDRH Portal). We have also developed the guidance document, “*Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments*” (Small Business Guidance) (April 2018), (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification>), which describes criteria FDA will use to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees, and which provides respondents instruction on submitting relevant information to FDA.

On December 29, 2022, the Consolidated Appropriations Act, 2023 (“Omnibus”) was signed into law. Section 3309 of the Omnibus — “Small Business Fee Waiver” — amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by amending section 738(a)(3)(B) to, among other items, allow FDA to offer registration fee waivers to small businesses experiencing financial hardships.

Consistent with the amendment, in the Federal Register of February 22, 2024 (89 FR 13349); “Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request”) FDA made available for comment proposed updates to the Small Business Guidance that describe how small businesses can show financial hardship to qualify for a small business fee waiver. Manufacturers seeking the small business fee waiver may provide evidence of a reported \$1,000,000 or less of gross receipts or sales in its most recent Federal income tax return, as well as evidence that they have filed a petition for bankruptcy and that the bankruptcy is currently active. The guidance updates also reflect how firms based in jurisdictions without a national taxing authority (NTA) need not submit a certification from their NTA to be eligible for fee waivers or reductions.

Additionally, FDA is proposing to consolidate the forms (FDA 3602 “*MDUFA Small Business Certification Request for a Business Headquartered in the United States*” and FDA 3602A “*MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States*”) into a single webform (MDUFA Small Business Request (“MDUFA SBR”, FDA 3602N)) to be completed by foreign as well as U.S. businesses/applicants and submitted via FDA’s Center for Devices and Radiological Health (CDRH) Customer Collaboration Portal (“CDRH Portal”) (<https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>). We have also added to the webform a “Registration & Listing Waiver” section which asks if the business/applicant will apply for a registration and listing fee waiver and whether they have applied in the past. Applicants seeking this waiver will be asked to include proof of bankruptcy documentation in the supporting documentation section.

We are therefore requesting OMB approval for revision of the information collection supporting MDUFA small business qualification, and the associated forms and instructional guidance discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA is the sole user of the information collected via the MDUFA SBR webform. The webform also serves to help entities understand the statutory requirements they must meet to qualify as a MDUFA small business or a small business experiencing financial hardship. The information submitted on the MDUFA SBR is used to determine whether the entity meets the requirements of section 738(d)(2)(A), (e)(2)(A), and (a)(3)(B) of the FD&C Act. Our review of the information helps ensure that the entity has identified all of its affiliates, partners, and parent firms, and that the total gross receipts and sales of the entity (including all affiliates, partners, and parent firms) is no more than \$100 million. If the entity qualifies as a MDUFA small business, FDA will inform the entity that it is eligible for reduced or waived fees for medical device applications it submits to FDA. Manufacturers that report less than \$1,000,000 in gross receipts or sales in their most recent income tax return (including the returns of its affiliates) may also be eligible to receive a waiver of the fee required for their annual registration (excluding the initial registration) if FDA determines that paying the annual registration fee represents a financial hardship to the manufacturer.

3. Use of Improved Information Technology and Burden Reduction

Section 738(d)(2)(B) and (e)(2)(B) of the FD&C Act specifically requires an entity to submit “a copy of its most recent Federal income tax return ... and a copy of such returns of its affiliates, partners, and parent firms” to demonstrate it qualifies as a MDUFA small business. The information will be collected via the MDUFA SBR webform and submitted online to FDA using CDRH Portal. Respondents may visit the website “[Reduced Medical Device User Fees: Small Business Determination \(SBD\) Program](https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program)” (<https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program>) for detailed instructions on accessing and completing a MDUFA SBR.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

No undue burden is imposed on small entities of the information collection. Rather, this information collection helps implement alternative fee schedules and waivers for entities that qualify.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements. Respondents submit the necessary information occasionally.

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 the Federal Register of February 22, 2024 (89 FR 13349), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, but they were not related to the information collection.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted FDA’s Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), the PII is collected in the context of the subject individuals’ professional capacity and FDA-related performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via the MDUFA SBR webform is taxpayer I.D., name, address, telephone number, email address, title, and bankruptcy documentation. Information collected via the MDUFA SBR webform 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 the MDUFA SBR webform will complete and submit it via the CDRH Customer Collaboration Portal. 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 of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
MDUFA Small Business Request	4,500	1	4,500	1	4,500

The MDUFA SBR webform is submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business or a small business experiencing financial hardship. The guidance document, “[Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments](#),” describes the criteria FDA uses to determine whether an entity qualifies as a MDUFMA small business and is eligible for a reduction or waiver of user fees.

This estimated burden is based on the number of applications received in the last few years and includes time to collect the required information. Based on our experience with this information collection, FDA estimates it will take respondents 1 hour to complete.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate includes the salaries for personnel who prepare the information. We expect that approximately half of the hour burden will be work performed by an Accountant* and approximately half by a Regulatory Affairs Professional.**

* The estimated hourly wage rate for an Accountant is based on the mean hourly wage rate for Accountants and Auditors, \$43.65 (May 2023 Bureau of Labor and Statistics data, occupation code 13-2011, http://www.bls.gov/oes/current/oes_nat.htm#13-0000), then doubled to account for benefits and overhead, and rounded to the nearest dollar.

**The estimated hourly wage rate for a Regulatory Affairs Professional is based on the mean hourly wage rate for a Lawyer, \$84.84 (May 2023 Bureau of Labor and Statistics data, occupation code 23-1011, https://www.bls.gov/oes/current/oes_nat.htm#23-0000), then doubled to account for benefits and overhead, and rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Accountants	2,250	\$87	\$195,750
Regulatory Affairs	2,250	\$170	\$382,500
Total			\$578,250

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

FDA will review each submission and the accompanying documentation to confirm the accuracy of information provided for an entity and to ensure that the entity qualifies as a “small business” within the meaning of MDUFMA. For entities requesting a registration fee waiver, FDA will also review accompanying bankruptcy documentation. As part of its review, FDA will review commercial databases to determine whether the entity has any affiliates, partners, or parent firms that it did not identify on the forms. FDA believes it will expend approximately 1 hour of effort on each form.

We doubled the hourly rate for a GS-13, step 10 employee (\$73.48)* to account for overhead (\$147 per hour, rounded to the nearest dollar). With 4,500 submissions, FDA estimates that the total cost to the Federal government will be \$661,500.

*U.S. Office of Personnel Management, Salary Table 2024-DCB, GS-13, step 10: [Pay & Leave : Salaries & Wages - OPM.gov](https://www.opm.gov/policy-data-oversight/salaries-grades/).

15. Explanation for Program Changes or Adjustments

We have proposed updates to the guidance document, “[Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments](#),” consistent with amendments to section 738(a)(3)(B) of the FD&C Act, as described in section 1 of this supporting statement.

Once the updates to the guidance document are published, we will consolidate forms FDA 3602 and FDA 3602A into a single webform, the “MDUFA Small Business Request” (MDUFA SBR, FDA 3602N) to be completed online by foreign and domestic businesses and submitted to FDA via the CDRH Customer Collaboration Portal (CDRH Portal), and remove reference to forms FDA 3602 and FDA 3602A via an 83C non-substantive change request. We have also added to the form a “Registration & Listing Waiver” section which asks if the business/applicant will apply for a registration and listing fee waiver and whether they have applied in the past. Applicants seeking this waiver will be asked to include proof of bankruptcy documentation in the supporting

documentation section. Because we assume that current bankruptcy documentation is readily available to applicants, we assume no change to the Average Burden per Response for this information collection.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our total burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

As required by the PRA and consistent with established agency practice, FDA will inform respondents of the OMB control number and current expiration date. However, because guidance documents are more frequently being accessed electronically, we are making technological updates to display the expiration date by linking to approval information found at <https://www.reginfo.gov/public/>. We intend to include the OMB control number and expiration date on the guidance document landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval of associated information collection. We are taking this approach to improve compatibility with current website platforms utilized by FDA.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.