

United States Food & Drug Administration

MEDICAL DEVICE USER FEE SMALL BUSINESS QUALIFICATION AND
CERTIFICATION

OMB Control No. 0910-0508

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 2017 from October 1, 2017, until September 30, 2022. 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.

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*.” 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*” (April 2018), available at <https://www.fda.gov/media/93354/download>, 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.

We are therefore requesting extension of OMB approval for 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 forms FDA 3602 and FDA 3602A. The forms also serve to help entities understand the statutory requirements they must meet to qualify as a MDUFA small business. We use the information submitted on forms FDA 3602 and FDA 3602A to determine whether the entity meets the requirements of section 738(d)(2)(A) and (e)(2)(A) 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 all medical device applications it submits to FDA.

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. At this time, FDA does not collect the information electronically. However, we are considering the feasibility of collecting the information by electronic means in the future.

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 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 December 23, 2021 (86 FR 72983), we published a 60-day notice requesting comment on the information collection. One comment was received but did not respond to the functional elements solicited in our 60-day notice or suggest a revision to our burden estimate.

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 Form FDA 3602 (MDUFA Small Business Certification Request) is taxpayer I.D., name, address, telephone number, email address, and title. The PII

submitted via Form FDA 3602A (MDUFA Foreign Small Business Certification Requests) is taxpayer I.D., name, address, telephone number, email address, and title. Information collected via Form 3602 and 3602A 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 3602 and 3602A 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 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

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3602-- MDUFA Small Business Certification Request For a Business Headquartered in the United States	2,500	1	2,500	1	2,500
FDA 3602A--MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					4,500

Forms [FDA 3602](#) and [FDA 3602A](#) are submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business. 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 in user fees.

This estimated burden is based on the number of applications received in the last few years and includes time required to collect the required information. Based on our experience with forms FDA 3602 and FDA 3602A, FDA believes it will take respondents 1 hour to complete either form.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate includes the salaries for personnel who prepare the forms. 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, \$39.26 (May 2020 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, \$71.59 (May 2020 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	\$79	\$177,750
Regulatory Affairs	2,250	\$143	\$321,750
Total			\$499,500

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 form FDA 3602 and FDA 3602A and each accompanying Federal income tax return 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. 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 employee (\$64.59)* to account for overhead (\$129 per hour, rounded to the nearest dollar). With 4,500 submissions, FDA estimates that the total cost to the Federal government will be \$580,500.

*U.S. Office of Personnel Management, Salary Table 2021-DCB, GS-13, step 10: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB_h.aspx

15. Explanation for Program Changes or Adjustments

We have adjusted the number of respondents to reflect recent annual submissions. This results in a decrease of 2,500 hours and responses annually.

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.