Medical Device User Fee Small Business Qualification and Certification
0910-0508
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Abstract
The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) requires FDA to collect a user fee from each person who submits certain medical device applications for FDA review. See section 738(a)(1) and (a)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j(a)(1) and (a)(2)) http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapVII-partC-subpart3-sec379j.pdf. A "small business" is eligible for reduced or waived fees. If an applicant does not provide information to FDA demonstrating to FDA's satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

Sections 738(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.

Both forms, FDA 3602 and FDA 3602A, are accessible through the guidance document, "Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf and downloadable on the internet at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/MedicalDeviceForms/default.htm. This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria.

2. Purpose and Use of the Information Collection

FDA is the sole user of the information collected through Forms FDA 3602 and FDA 3602A. The forms will also serve to help entities understand the statutory requirements they must meet to qualify as a "small business."

FDA will use the information submitted on Forms FDA 3602 and FDA 3602A to decide whether the entity meets the requirements of section 738(d)(2)(A) and (e)(2)(A) of the FD&C Act. FDA's review of each form will ensure that the entity has identified all of its affiliates, partners, or parent firms, and that the total gross receipts and sales of the entity (including all affiliates, partners, or parent firms) is no more than $100 million. If the entity qualifies as a "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" as evidence that it qualifies as a MDUFMA 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

Forms FDA 3602 and FDA 3602A do not duplicate any other information collection.

5. Impact on Small Businesses or Other Small Entities

Forms FDA 3602 and FDA 3602A collect the minimum information FDA requires to efficiently and quickly determine whether an entity is a small business. Section 738(d)(2)(B) and (e)(2)(B) of the FD&C Act specifies the evidence that an entity must submit to qualify for small business fees or waivers. The information collection has been held to the absolute minimum required for the intended use of the data. Approximately 90% of entities that submit an application qualify as a MDUFMA small business.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to this information collection occasionally.

MDUFMA requires FDA to collect a user fee from each person who submits certain medical device applications for FDA review (see section 738(a)(1) and (c)(5) of the FD&C Act). A "small business" is eligible for reduced or waived fees. This information collection allows FDA to determine whether an entity is a small business under section 738(d)(2)(A) and (e)(2)(A) of the FD&C Act. Only applicants that would like to be considered a small business will respond to the collection. If an applicant does not provide the information to FDA, the applicant must pay the standard (full) fee for any application it submits. There are no legal obstacles to reduce the burden.

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 November 14, 2018 (83 FR 56852). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is trade secret or confidential commercial information is subject to FDA's regulations on the release of information, 21 CFR Part 20.

Analysis of Potential Privacy Risks and Requirements/Assurance of Privacy

In renewing this ICR, 21 U.S.C. 738(d)(2)(A) and (e)(2)(A), staff from FDA's Center for Devices and Radiological Health, Office of the Center Director consulted the Center for Devices and Radiological Health, Office of Communications and Education, Division of Information Disclosure and the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA in association with the Medical Device User Fee Small Business Qualification and Certification Data Collection, if finalized as proposed. The Medical Device User Fee Small Business Qualification and Certification Data Collection does solicit PII that will be collected and maintained by FDA. 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). PII collected on form 3602 is submitter name, taxpayer ID number, mailing address, email address, and telephone number. PII collected on form 3602A is submitter name, taxpayer ID number, mailing address, email address, telephone number, and two title options are provided (Head of Firm or Chief Financial Officer).

FDA further determined that it maintains the PII and other information collected via submitted forms in a set of systems that is subject to the Privacy Act of 1974. The forms display the Privacy Act notice statement required under the Act (5 U.S.C. 552a(e)(3)). FDA has published a System of Records Notice (SORN) for User Fee program records, SORN No. 09-10-0021, FDA User Fee System, HHS/FDA.

FDA also minimized the PII to be collected to protect the privacy of the individuals. To ensure against the solicitation or submission of unnecessary PII, FDA designed the forms to provide fields soliciting only information required to meet the intended purpose behind the forms.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

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 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	5,000	1	5,000	1	5,000
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					7,000

This burden is based on the number of applications received in the last 3 years and includes time required to collect the required information. Based on our experience with Form FDA 3602, FDA believes it will take each respondent 1 hour to complete the form.

Based on our experience with Form FDA 3602A, FDA believes that it will take each respondent 1 hour to complete.

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 annualized cost burden estimate is based on the mean hourly wage rate for an Accountant, $37.46,* and the estimated hourly wage rate for a Regulatory Affairs Professional, $72.**

*May 2017 Bureau of Labor and Statistics data, occupation code 13-2011 Accountants and Auditors, http://www.bls.gov/oes/current/oes_nat.htm#13-0000.

**The estimated hourly wage rate for a Regulatory Affairs Professional is based on the average total compensation for a Regulatory Affairs professional, $150,422, in the Regulatory Affairs Professionals Society's "2016 Scope of Practice & Compensation Report for the Regulatory Profession" (p.11, https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, viewed on 10/26/18). The hourly rate assumes a 40-hour work week and has been rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Accountants	3,500	$37.46	$131,110
Regulatory Affairs	3,500	$72.00	$252,000
Total			$383,110

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 FDA Forms 3602 and 3602A. FDA believes it will have to expend approximately 1 hour of effort on each FDA Form 3602 and 3602A. We doubled the hourly rate for a GS-13 employee ($60.40)* to account for overhead (total, $121 per hour). With 7,000 submissions to be reviewed, FDA estimates that the total cost to the Federal government will be $847,000.

*U.S. Office of Personnel Management, Salary Table 2018-DCB, GS-13, step 10 (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf)

15. Explanation for Program Changes or Adjustments

We made non-substantive changes in form FDA 3602 to correct an error (signature block referred to the person listed in #5, but #5 was a phone field) and to make forms 3602 and 3602a and their instructions "evergreen," by including a space for the applicant to fill in the appropriate Fiscal Year (FY). This will eliminate the need to revise the FY on the forms each year.

Our estimated burden for the information collection reflects an overall increase of 2,000 hours and a corresponding increase of 2,000 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Inadvertently the guidance document, "Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments", was removed from ROCIS during the last renewal. Both forms are accessible through the guidance document and downloadable on the internet.

16. Plans for Tabulation and Publication and Project Time Schedule

Not applicable.

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.