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; small business fees for fiscal year (FY) 2012. 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 available in the guidance document, "Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments: FY 2012 Medical Device User Fee Small Business Qualification and Certification." http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM267051.pdf. 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 for FY 2012.

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 during FY 2012.

The respondents to this information collection are private sector businesses or other for-profit entities.

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. Most of the respondents are businesses. 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.

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 is 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 April 18, 2012 (77 FR 23267). 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.

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[1]

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3602	4,200	1	4,200	1	4,200
3602A	900	1	900	1	900
Total					5,100

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, $33.15,* and the estimated hourly wage rate for a Regulatory Affairs Professional, $45.46.**

*May 2010 Bureau of Labor and Statistics data, occupation code 13-2011 Accountants and Auditors, http://www.bls.gov/oes/current/oes132011.htm.
**The estimated wage rate for a Regulatory Affairs Professional is an average of the annual wage rates listed in several sources including Salary.com, eHow.com, MDDIonline.com, and Recruiter.com. The hourly wage rate assumes a 40-hour work week.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Accountants	2,550	$33.15	$84,533
Regulatory Affairs	2,550	$45.46	$115,923
Total			$200,456

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 ($55.46)* to account for overhead (total, $111 per hour). With 5,100 submissions to be reviewed, FDA estimates that the total cost to the Federal government will be $566,100.

*U.S. Office of Personnel Management, Salary Table 2012-DCB, GS-13, step 10 (http://www.opm.gov/oca/12tables/html/dcb_h.asp)

15. Explanation for Program Changes or Adjustments

The total reporting burden hours have been adjusted due to an increased number of respondents participating in the program. This resulted in an increase of 1,529 hours and 1,529 respondents.

For clarity and accuracy, the two line items for Form FDA 3602A are now expressed as a single line item in the reporting burden table. We also adjusted the ICR title, formerly

"Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification," to "Medical Device User Fee Small Business Qualification and Certification" to more simply describe the collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Not applicable.

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

FDA is not seeking an exemption to display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.