Guidance for Industry, FDA, and Foreign Governments: FY 2010 Medical Device User Fee Small Business Qualification and Certification
0910-0508
SUPPORTING STATEMENT

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 § 738(a)(1) and § 738(c)(5) of the Federal Food, Drug, and Cosmetic Act (all further citations in this notice are to that act).
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVIIGeneralAuthority/ucm111075.htm A "small business" is eligible for reduced or waived fees; small business fees for FY 2010. 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 738(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 FDA Forms 3602 and 3602A are available in the guidance document, "Guidance for Industry, FDA, and Foreign Governments: FY 2010 Medical Device User Fee Small Business Qualification and Certification."
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.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 2010.

The information collection for FDA Form 3602 is currently approved under OMB control number 0910-0508. The information collection for FDA Form 3602A is currently approved under OMB control number 0910-0613. FDA Forms 3602 and 3602A are now in a single guidance document. With this request for approval, FDA is requesting to consolidate OMB approvals 0910-0508 and 0910-0613 into one information collection using the OMB control number 0910-0508.

This information is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information Collection

FDA is the sole user of the information collected through FDA Forms 3602 and 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 FDA Forms 3602 and 3602A to decide whether the entity meets the requirements of § 738(d)(2)(A) and § 738(e)(2)(A). 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 2010.

The respondents for this information collection are Private Sector; business or other for-profit.

3. Use of Improved Information Technology Burden Reduction

Because § 738(d)(2)(B) and § 738(e)(2)(B) specifically require 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, FDA is not providing for the use of improved information technology for FY 2010.

4. Efforts to Identify Duplication and Use of Similar Information

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

5. Impact on Small Businesses or Other Small Entities

FDA Forms 3602 and 3602A collect the minimum information FDA requires to efficiently and quickly determine whether an entity is a small business. Because § 738(d)(2)(B) and § 738(e)(2)(B) specify the evidence that an entity must submit to qualify for small business fees or waivers, there is no way to reduce the information collection. Most of the respondents are businesses.

The information being requested or required has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Data Less Frequently

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 § 738(a)(1) and § 738(c)(5) of the Federal Food, Drug, and Cosmetic Act (all further citations in this notice are to that act).

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

FDA consulted with an association that represents small medical device manufacturers, and we used information from previous discussions with small manufacturers and industry to estimate the number of entities that will choose to submit a FDA Form 3602 or 3602A.

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 10/23/2009 (74 FR 54826).
http://edocket.access.gpo.gov/2009/pdf/E9-25538.pdf
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	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000
3602A Sections I and II	340	1	340	1	340
3602A Section III	33	7	231	1	231
					3,571

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

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 FDA Form 3602, FDA believes each business will require 1 hour to complete Sections I and II.

Based on our experience with FDA Form 3602A, FDA believes that it will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification however, FDA believes that it will require less than 1 hour to complete due to simplicity of the form.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Accountants	1,785	$50.00	$89,250
Regulatory Affairs	1,786	$75.00	$133,950
Total			$223,200

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 FDA Form 3602 and 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 data bases 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 ($43) to account for overhead.(total, $86 per hour). With 3,571 submissions to be reviewed, FDA estimates that the total cost to the Federal government will be $307,106.

15. Explanation for Program Changes or Adjustments

The adjustment of 1,571 respondents and hours are due to a result of increased number of respondents participating in the program.

16. Plans for Tabulation and Publication and Project Time Schedule

Not applicable.

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

FDA will display an expiration date on the FDA Forms 3602 and 3602A.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.