SUPPORTING STATEMENT
Medical Device User Fee and Modernization Act Small Business Qualification Certification
Form FDA 3602
0910-0508

A. JUSTIFICATION

1. Necessity of the Information Collection

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. MDUFMA user fees for FY 2007 ranged from $3,326 to $281,600, depending on the type of application. See § 738(a)(1) and § 738(c)(5) (Attachment 1) of the Federal Food, Drug, and Cosmetic Act (all further citations in this notice are to that act). A "small business" is eligible for reduced or waived fees; small business fees for FY 2007 range from $3,326 to $107,008. 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.

The FY 2007 MDUFMA Small Business Qualification Certification (hereafter referred to as Form FDA 3602) (Attachment 2) will permit an applicant to certify that it qualifies as a "small business" within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided. Instructions on how to complete Form FDA 3602 can be found in the Guidance for Industry and FDA: FY 2007 MDUFMA Small Business Qualification Worksheet and Certification at: http://www.fda.gov/cdrh/mdufma/guidance/2007.pdf

Sections 738(d)(2)(A) and 738(e)(2)(A) (Attachment 1) 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.]

2. How, by Whom, and for What Purpose Information is Used

FDA is the sole user of the information collected through a Form FDA 3602. The form itself 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 Form FDA 3602 to decide whether the entity meets the requirements of § 738(d)(2)(A) and § 738(e)(2)(A). FDA's review of each Form FDA 3602 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 2007.

3. Use of Improved Information Technology

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 2007.

4. Identification of Duplication and Similar Information Already Available

Form FDA 3602 does not duplicate any other information collection.

5. Small Business

Form FDA 3602 collects 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.

6. Consequences if Data Were Collected Less Frequently

Data is collected only once for FY 2007.

7. Special Circumstances

MDUFMA was enacted October 26, 2002. An applicant must pay the standard (full) fee unless FDA decides the applicant is a "small business" within the meaning of MDUFMA. FDA cannot make this determination for FY 2007 unless we have the information collected on and with the Form FDA 3602.

8. Outside Consultation

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 Form FDA 3602.

In the Federal Register of August 29, 2006 (71 FR 51196), (Attachment 3) FDA requested comments on the information collection from the public. No comments were received.

9. Gifts

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

10. Confidentiality

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. Sensitive Information

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

12. Respondent Hour Burden and Annualized Burden Cost Estimates

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form Number	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
Form FDA 3602	2,000	1	2,000	1	2,000	$88

[1]There are no capital 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, to copy each required Federal income tax return, and to complete the form. FDA believes most entities that submit a Form FDA 3602 will not have any affiliates, partners, or parent firms; FDA believes very few will have more than three or four affiliates, partners, or parent firms.

13. Annual Cost Burden to Respondent

The total cost burden (1 hour, for a total cost of $88) is attributable to completion and submission of the Form FDA 3602 and copying and including a copy of each required Federal income tax return.

14. Annualized Cost to the Federal Government

FDA will review each Form FDA 3602 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 Form FDA 3602. FDA believes it will have to expend approximately 1 hour of effort on each Form FDA 3602. We doubled the hourly rate for a GS-14 ($44) to account for overhead (total, $88 per hour). With 2,000 submissions to be reviewed, FDA estimates that the total cost to the Federal government will be $176,000.

15. Changes or Adjustments in Burden

An adjustment (decrease) in the burden hours was recognized due to the number of respondents participating in the program.

16, Statistical Analysis, Publication Plans, and Schedule

Not applicable.

17. Approval Not to Display Expiration Date

FDA will display an expiration date on the Form FDA 3602.

18. Exceptions to the Certification Statement Identified in Item 19

No excepts to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

FDA does not plan to publish the information collected under the provisions of this proposed regulation for statistical use. This collection of information does not employ statistical methods.