**SUPPORTING STATEMENT**
Guidance for Industry, FDA, and Foreign Governments
FY 2008 Medical Device User Fee Small Business Qualification and Certification
Form FDA 3602A
OMB Control No. 0910-0613

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## A. JUSTIFICATION

### 1. Necessity of the Information Collection

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation, the Medical Device User Fee Amendments of 2007, http://www.fda.gov/cdrh/mdufma/provisions.pdf, is part of a larger bill, the Food and Drug Administration Amendments Act of 2007 (FDAAA) that affects many other FDA programs. The FDAAA made significant changes to the medical device user fee provisions of the Federal Food, Drug, and Cosmetic Act. Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) and Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is amended which provides a new way for a foreign business to qualify as a "small business" eligible to pay a significantly-lower fee when a medical device user fee must be paid.

Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the only way a business could qualify as a "small business" was to submit a Federal (U.S.) income tax return showing its gross receipts or sales did not exceed a statutory threshold (currently, $100 million). If the business could not provide a Federal income tax return, it could not qualify as a small business and must pay the standard (full) fee. Since many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates.

In lieu of a Federal income tax return, the FDAAA will allow a foreign business to qualify as a "small business" by submitting a certification from its "national taxing authority," the foreign equivalent of the United

States Internal Revenue Service. This certification, referred to as a "National Taxing Authority Certification," must:

- be in English;
- be from the national taxing authority of the country in which the business is headquartered;
- provide the business's gross receipts or sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in converting local currency to U.S. dollars;
- provide the dates during which the reported receipts or sales were collected; and
- bear the official seal of the national taxing authority.

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

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

FDA will use the information submitted on Form FDA 3602A to decide whether the foreign business meets the requirements of § 738(d)(2)(A) and § 738(e)(2)(A). FDA's review of each Form FDA 3602A will ensure that the entity has identified all of its affiliates 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 any reduced or waived fees that are applicable to the medical device applications it submits to FDA annually during FY 2008-FY 2012.

The FY 2008 MDUFMA Foreign Small Business Qualification Certification is included in the guidance, "**Guidance for Industry, FDA, and Foreign Governments: FY 2008 Medical Device User Fee Small Business Qualification and Certification"**, which is available at: http://www.fda.gov/cdrh/mdufma/guidance/2008.pdf. (Hereafter referred to as Form FDA 3602A) (Attachment 1) will accomplish three key objectives —

- It will permit a foreign business to certify that it qualifies as a "small business" within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA);
- It 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;
- It will permit the National Taxing Authority to convert the foreign business's reported incomes to "gross receipts or sales" in U.S. dollars and provide the required National Taxing Authority Certification. This will provide FDA assurance that the foreign business meets the statutory income threshold.

**3. Use of Improved Information Technology**

Because the 2007 Amendments will require each Form FDA 3602A to "bear the official seal of the national taxing authority," FDA is not, at this time, providing for the use of improved information technology.

**4. Identification of Duplication and Similar Information Already Available**

Form FDA 3602A does not duplicate any other information collection.

**5. Small Business**

Form FDA 3602A collects the minimum information FDA requires to efficiently and quickly determine whether a foreign business entity qualifies as a small business.

**6. Consequences if Data Were Collected Less Frequently**

Data is collected only once each year for each business seeking small business status. This is the minimum frequency permitted by sections 738(d) and (e).

**7. Special Circumstances**

There are no special circumstances for this collection of information.

**8. Outside Consultation**

In the FEDERAL REGISTER of January 15, 2008 (73 FR 2503), FDA published a 60-day notice requesting public comment on the information collection provisions. In response to this notice, FDA received two general comments on the information collection requirements which are described below, and FDA response.

(Comment 1) The commenter recommended that once a firm has qualified for small business status, this should be good enough for 3-5 years. Further, that it would be quite unlikely that a small business firm would move from a small business to a huge business in three years, particularly for the starting business or very small business. The commenter concluded that the extra paperwork will cost time and money for the industry and FDA as well.

(Response) FDA cannot accept this recommendation, because current provisions of the 2007 Amendments does not permit the recommended approach. Sections 738(d)(2)(B) and 738(e)(2)(B), define the " Evidence of Qualification" that must be provided to qualify as a small business. These provisions specifically require the applicant to support its claim that it qualifies as a small business by submitting, among other things, either:

"a copy of the most recent Federal income tax return for the taxable year" or

"a signed certification… gross receipts or sales for the most recent year."

Because both requirements specify that the information must be for the "most recent" year, FDA cannot determine whether an applicants` status as a small business, will persist for a period of more than one year.

(Comment 2) The commenter expressed concern there could be some problems in collecting the tax certification information required of FDA form

3602 A Section III, from National Taxing Authorities of each country where an applicant has business entities. The commenter cited that in some countries, National Taxing Authorities may not agree to fill out this form for various reasons including: (1) The fact that it may not be their own official form, (2) the form is in English and (3) authorities do not agree to determine the exchange rate for the United States dollar.

As an alternative to FDA form 3602A Section III, the commenter recommends the following information be provided:

- A tax report or an income statement from each country of business entities,
- Translation to English could be organized by the applicant, and a
- Determination of exchange rate could be done by the applicant.

(Response) FDA cannot accept this recommendation because the agency does not have authority to modify the statutory requirement for a signed certification form, and bearing the seal of the national taxing authority of the country in which the applicant or if applicable, affiliate is headquartered. ( see §§ 738 (d)(2)(B)(iii) and 738 (e)(2)(B)( iii) )

FDA also 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 would seek small business status.

**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 3602A | Number of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Sections I and II (completed by the business seeking "small business" status) | 229 | 1 | 229 | 1 | 229 |
| Section III (completed by the foreign national taxing authority) | 33 | 7 | 231 | 1 | 231 |
| Total Burden | | | | | 460 |

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

We estimated the number of respondents as follows:

| Projected Annual Foreign Medical Device Submissions Under the 2007 Amendments | | | |
|---|---|---|---|
| Type of Submission | Total Projected Submissions | Foreign Submissions* (16%) | Small Business* (25%) |
| Premarket Application (PMA, BLA, PDP, PMR) | 60 | 10 | 3 |
| Supplement (all types) | 400 | 64 | 16 |
| 30-day Notice | 550 | 88 | 22 |
| 510(k) | 4,000 | 640 | 160 |
| 513(g) | 300 | 48 | 12 |
| Class III Device Subject to Periodic Reporting | 400 | 64 | 16 |
| Total Submissions | 5,710 | 914 | 229 |

This burden estimate is based on an examination of PMAs, PMA supplements, and 510(k) premarket notifications received from foreign businesses during FY 2006, an examination of the number of PMAs held by foreign businesses that are currently subject to periodic reporting, and FDA's estimation of the time required to collect the required information to complete the form. The evidence supporting each 3602A must be reviewed by a foreign national taxing authority to complete Section III, the National Taxing Authority Certification, of each 3602A.

FDA believes most entities that submit a Form FDA 3602A will not have any affiliates and very few will have more than three or four affiliates. Based on our experience with Form FDA 3602, FDA believes each business will require one hour to complete Sections I and II. Because this is a new requirement, FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification. Based on similar information collected by FDA Form 3602 and FDA Form 3602A, FDA believes it is reasonable to estimate that the national taxing authority will require one hour to complete Section III.

**Cost to Respondents**

The total cost burden of $180 per hour is attributable to completion and submission of the form FDA 3602A.

**Annual Cost Burden to Respondents**

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

**13. Annualized Cost to the Federal Government**

Using these estimates, the total burden of each 3602A is expected to be two hours. With 229 3602 as expected, the total burden is expected to amount to 458 hours. Using the hourly rate of a GS-14 ($45), the total burden cost is $20,610 ($10,305 on the small businesses completing Sections I and II, and $10,305 on the national taxing authorities completing Section III).

**15 Changes or Adjustments in Burden**

There are no changes or adjustments in the burden for this information collection

**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 3602A.

**18. Exceptions to the Certification Statement Identified in Item 19**

No exceptions 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.