SUPPORTING STATEMENT
Agency Emergency Processing Under OMB Review: Medical Device User Fee Amendments of 2007: Foreign Small Business Qualification Certification Form FDA 3602 A

A. JUSTIFICATION

1. Necessity of the Information Collection

Congress recently passed an omnibus FDA bill that included the "Medical Device User Fee Amendments of 2007" (the 2007Amendments). The 2007 Amendments reauthorized the medical device user fees for fiscal years 2008 through 2012 and made significant changes to the medical device user fee provisions of the Federal Food, Drug, and Cosmetic Act (the Act). The 2007 Amendments will provide 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 existing law, 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 that did not exceed a statutory threshold (currently, $100 million). If the business could not provide a Federal income tax return, it did not qualify as a small business and had to 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 2007 Amendments 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 by 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 under § 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 annually to FDA for FY 2008 through FY 2012.

Form FDA 3602 A, "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 will be available at: http://www.fda.gov/cdrh/mdufma/guidance/2008.pdf.

Form FDA 3602A will accomplish the following 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 and

- 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

The FDA publish an emergency notice in the **Federal Register** of October 2, 2007 (72 FR 56077) soliciting public comment on the proposed collection of information. In response to that notice, 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]

21 U.S.C. 379j / 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[2]	229	1	229
				Total Burden	458

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

We estimated the number of small business 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%)
Pre market 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

We estimated the number of national taxing authorities by counting the number of nations from which FDA received 510(k) pre market notifications for FY 2006. This burden estimate is based on an examination of: (1) PMAs, PMA supplements and 510(k) pre market notifications received from foreign businesses for FY 2006; (2) an examination of the number of PMAs held by foreign businesses that are currently subject to periodic reporting, and (3) FDA's estimation of the time required to collect the required information to complete the form. The information supporting each 3602 A, 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 who submit a Form FDA 3602A will not have affiliates with very few having more than three or four. Based on CDRHs 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 regarding the time that will be required to complete Section III of Form FDA 3602 A, i.e. the National Taxing Authority Certification. However, based on the similarity of 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 of Form FDA 3602 A.

Cost to Respondents

The total cost burden of $180 per hour is attributable to completion and submission of the Form FDA 3602A, (OMB control number 0910-0508.)

13. Annual Cost Burden to Respondents

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 require one hour for review of each 3602 A form and will retain a record copy for the minimum permissible period of time, to ensure the integrity of the process. We doubled the hourly rate of a GS-14 to account for the annualized costs to the Federal Government which is estimated to be $20,610.

15. Changes or Adjustments in Burden

This is a new 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

None

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.