and respond to STD outbreaks and trends in STD-associated risk behavior. Users of data include, but are not limited to, congressional offices, state and local health agencies, health care providers, and other health-related groups.

CDC disseminates all STD surveillance information through the MMWR series of publications, including the MMWR, the CDC Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, DSTDP publishes an annual STD-specific surveillance summary and supplements in hard copy on CD–ROM and on the Internet *http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm.*

CDC will use the findings from this and other STD surveillance to develop guidelines, control strategies, and impact measures that monitor trends in STDs in the United States.

We expect a total of 57 sites in state, city, and territory health departments will be submitting STD morbidity information to CDC each week.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden in hours
States	50	52	20/60	867
Territories	5	52	20/60	87
Cities	2	52	20/60	35
Totals	57			989

Dated: April 3, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–7575 Filed 4–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0027] (formerly Docket No. 2007N–0495)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 12, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0613. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A—(OMB Control Number 0910–0613)—Extension

The FDA Amendments Act of 2007 includes the ''Medical Device User Fee Amendments of 2007'' (the 2007 Amendments), which reauthorizes medical device user fees for fiscal years (FY) 2008 through 2012 and which makes significant changes to the medical device user fee provisions of the act. The 2007 Amendments 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.

Before passage of the 2007 Amendments, 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 a 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. Because 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. Thus, foreign governments, including the European Union, have objected.

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 our 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' gross receipts or sales for the most recent year, in both the local currency and in U.S. 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.

The new FDA Form 3602A, ''FY 2008 MDUFMA Foreign Small Business Qualification Certification,'' will collect the information required by the statute and allows a foreign business to qualify for the same small business benefits as a domestic U.S. business.

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 in this document along with FDA's responses.

(Comment 1) The commenter recommended that once a firm has qualified for small business status, this should be good enough for 3 to 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 3 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 do not permit the recommended approach. Section 738(d)(2)(B) and (e)(2)(B) of the act (21 U.S.C. 379j(d)(2)(B) and (e)(2)(B)) defines the ''Evidence of Qualification'' that must be provided to qualify as a small business. The provisions specifically require the applicant to support its claim that it qualifies as a small business by submitting, among other things, the following:

- ''a copy of the most recent Federal income tax return for a taxable year'' and
- A signed certification of 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 applicant's status as a small business will persist for a period of more than 1 year.

(Comment 2) The commenter expressed concern there could be some problems in collecting the tax certification information required of Form FDA 3602A, Section III, from the national taxing authority of each country where an applicant has business entities. The commenter cited that in some countries, the national taxing authority may not agree to fill out this form for various reasons including: (1) The fact that it may not be its own official form, (2) the form is in English, and (3) authorities do not agree to determine the exchange rate for the U.S. dollar.

As an alternative to Form FDA 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 section 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii)).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA 3602A	No. 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					460

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

This burden estimate is based on an examination of 510(k) premarket notifications received during FY 2006 and FDA's estimation of the time to collect the required information to complete Form FDA 3602A. The evidence supporting each Form FDA 3602A must be reviewed by a foreign national taxing authority to complete Section III, the National Taxing Authority Certification, of each Form FDA 3602A. Because this is a new activity, and neither FDA nor any foreign national taxing authority has any data that would provide an objective measure of the effort required to complete Section III, FDA is estimating that the burden will be the same as FDA experiences in reviewing Form FDA 3602, ''FY 2008 MDUFMA Small Business Qualification Certification For a Business Headquartered in the United States,'' approved under OMB control number 0910–0508.

FDA believes most entities that submit Form FDA 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602, FDA believes each business will require 1 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.

Dated: April 7, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7637 Filed 4–9–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0213] (formerly Docket No. 2007N–0460)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 12, 2008.