

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0359]

**Agency Emergency Processing Under OMB Review; 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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a new FDA foreign small business qualification certification form that will allow a foreign business to qualify as a “small business” and pay certain medical device user fees at reduced rates.

DATES: Fax written comments on the collection of information by *[insert date 3 days after date of publication in the Federal Register]*.

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-mail to baguilar@omb.eop.gov. All comments should be identified with the OMB Control Number 0910-NEW and the title “Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A; (21 U.S.C. 379j); Emergency Request.” Also

DDM
Display Date 10-1-07
Publication Date 10-2-07
Certifier D. Hawkins

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: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA, (44 U.S.C. 3507 (j) and 5 CFR 1320.13). The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), which expires September 30, 2007, amended section 738 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U. S.C. 379j) to provide FDA with new responsibilities and resources to keep up with the rapidly growing device industry and changing medical device technology. Congress recently passed an omnibus FDA bill that includes the “Medical Device User Fee Amendments of 2007,” (the 2007 Amendments), which will reauthorize medical device user fees for fiscal years 2008 through 2012 and will make significant changes to the medical device user fee provisions of 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. The user fee provisions of the 2007 Amendments provide for an October 1, 2007, effective date, and FDA expects foreign businesses will want to request small business status immediately upon enactment.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate

of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A; (21 U.S.C.379j); Emergency Request

Congress recently passed an omnibus FDA bill that includes the 2007 Amendments, which will reauthorize medical device user fees for fiscal years 2008 through 2012 and will makes significant changes to the medical device user fee provisions of 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 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. Since many foreign businesses have not, and cannot, filed 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 form, 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’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.

The new FDA Form 3602A, “ FY 2008 MDUFMA Foreign Small Business Qualification Certification,” will collect the information required by the statute and will allow a foreign business to qualify for the same small business benefits as a domestic U.S. small business. The user fee provisions of 2007 Amendments provide for an October 1, 2007, effective date, and FDA expects foreign businesses will want to request small business status immediately upon enactment.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

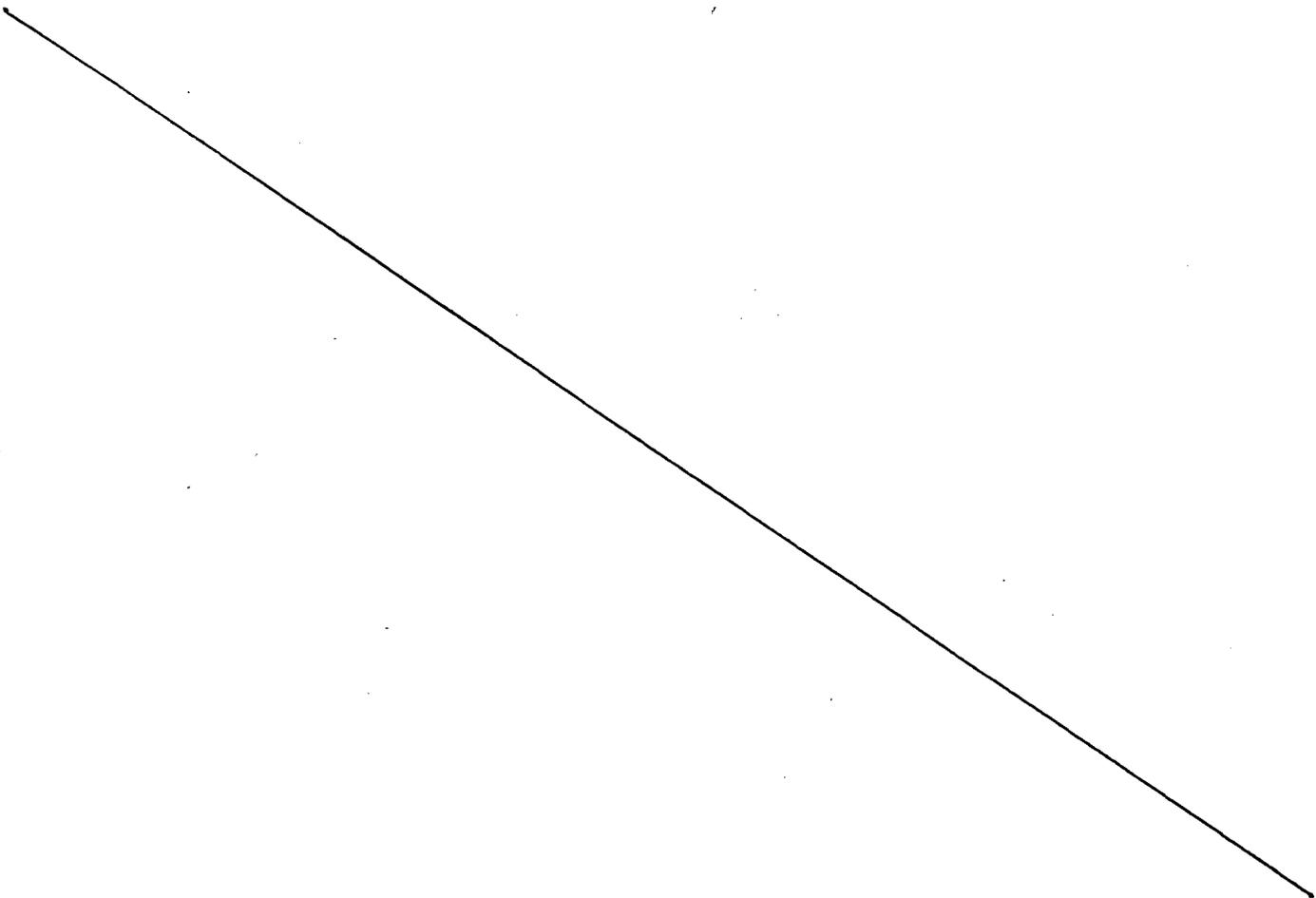
FDA Form 3602A	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Sections I and II (completed by the business seeking “small business” status)	229	1	229	1	229
Section III (completed by the foreign national taxing authority)	33	7	229	1	229
Total Burden					458

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

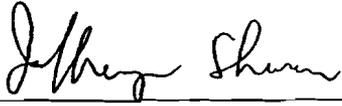
This burden estimate is based on an examination of 510(k) premarket notifications received during FY 2006 and FDA’s estimation of the time required to collect the required information to complete the form. The evidence

supporting each 3602A must be reviewed by a foreign national taxing authority to complete Section III, the National Taxing Authority Certification, of each 3602A. 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 the Form FDA 3602, approved under OMB control number 0910-0508.

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 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: SEP 26 2007
September 26, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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