Dated: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 October 5, 2007.

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 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 2007Amendments 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 BURDEN[1]

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

[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 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: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading it's scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on October 30, 2007, from 8 a.m. to 5:30 p.m.

Location: Washington DC North/ Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877, Salons A, B, and C.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, carlos.Peña@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will hear about and discuss the agency's critical path program. The Science Board will hear about and discuss updates on the National Antimicrobial Resistance Monitoring System (NARMS) Program and activities related to melamine from the March 31, 2006, and June 14, 2007, Science Board meetings. The Science Board will then hear about and discuss the subcommittee review of the agency's science programs. The Science Board will also hear about and discuss the agency's updates on drug safety.FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 15, 2007. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 5, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 8, 2007.