4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0324]

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification

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 [INSERT DATE 30 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: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0508. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-5156,

Daniel.Gittleson@fda.hhs.gov.

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.

Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification--(OMB Control Number 0910-0508)--Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107-250) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide for user fees for certain medical device applications. FDA published a Federal Register notice on August 1, 2011 (76 FR 45826), announcing fees for fiscal year (FY) 2012. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a "small business." This means there are two levels of fees; a standard fee and a reduced or waived small business fee. You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket

application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the "small business" criteria (Form FDA 3602, "FY 2012 MDUFMA Small Business Qualification Certification--For a Business Headquartered in the United States"). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a "small business" within the meaning of MDUFMA.

The 2007 Amendments provide an alternative 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 (Form FDA 3602A, "FY 2012 MDUFMA Foreign Small Business Qualification Certification--For a Business Headquartered Outside the United States"). 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.

Both Forms FDA 3602 and FDA 3602A are available in the guidance document, "Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments: FY 2012 Medical Device User Fee Small Business Qualification and Certification," available on the Internet at:http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM267051.pdf. This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2012.

The Form FDA 3602 burden is based on the number of applications received in the last 3 years. 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 Form FDA 3602A, FDA believes each business will require 1 hour to complete the form.

In the Federal Register of April 18, 2012 (77 FR 23267), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

| Form FDA No. | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| 3602 | 4,200 | 1 | 4,200 | 1 | 4,200 |
| 3602A | 900 | 1 | 900 | 1 | 900 |
| Total | | | | | 5,100 |

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

Dated: January 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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