4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4206]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 and title "Medical Device User Fee Small Business Qualification and Certification." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@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.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910-0508--Extension

Medical device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107-250). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the Food and Drug Administration Amendments Act of 2007 (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act of 2017 (MDUFA IV). MDUFA IV will be in place from October 1, 2017, until September 30, 2022.

A business that is qualified and certified as a "small business" is eligible for a substantial reduction in most of these user fees. The guidance document entitled "Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" describes the criteria FDA will use to decide whether an entity is eligible for a reduction in user fees and the process by which a business may request certification as a small business.

An applicant can qualify for a small business fee discount under MDUFMA if they reported gross receipts or sales of no more than $100 million on their Federal income tax return for the most recent tax year. If they have any affiliates, partners, or parent firms, the applicant

must add the gross receipts or sales of the affiliates, partners, or parent firms to the applicant's, and the total must be no more than $100 million. If the applicant's gross receipts or sales are no more than $30 million, including all of their affiliates, partners, and parent firms, they will also qualify for a waiver of the fee for their 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, "MDUFA Small Business Certification Request 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.

MDUFA II provided 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, "MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States"). Before passage of MDUFA II, 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 effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, objected. In lieu of a Federal income tax return, the MDUFA II allowed 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: (1) be in English; (2) be from the national taxing authority of the country in which the business is headquartered; (3) 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; (4) provide the dates during which the reported receipts or sales were collected; and (5) bear the official seal of the national taxing authority.

Forms FDA 3602 and FDA 3602A are accessible through the guidance document entitled "Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" on the internet at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf.

The estimated burden is based on the number of applications received in the last 3 years and includes time required to collect the required information. Based on our experience with Form FDA 3602, FDA believes it will take each respondent 1 hour to complete the form. Based on our experience with Form FDA 3602A, FDA also believes that it will take each respondent 1 hour to complete.

In the *Federal Register* of November 14, 2018 (83 FR 56852), 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]

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3602--MDUFA Small Business Certification Request For a Business Headquartered in the United States	5,000	1	5,000	1	5,000
FDA 3602A--MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					7,000

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

Our estimated burden for the information collection reflects an overall increase of 2,000 hours and a corresponding increase of 2,000 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: April 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-08471 Filed: 4/25/2019 8:45 am; Publication Date: 4/26/2019]