56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Crystal Allard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1518, Silver Spring, MD 20993–0002, 301–796–8856, *crystal.allard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is a participating member of PhUSE, an independent, non-profit consortium of academic, regulatory, non-profit, and private sector entities. PhUSE provides a global platform for the discussion of topics encompassing the work of biostatisticians, data managers, statistical programmers, and e-clinical information technology professionals, with the mission of providing an open, transparent, and collaborative forum to address computational science issues. As part of this collaboration, PhUSE working groups develop and periodically publish proposals for enhancing the review and analysis of human and animal study data submitted to regulatory agencies. You can learn more about PhUSE working groups at *http://www.phuse.eu/cs-working-groups.aspx.* (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

In December 2014, FDA published the Study Data Technical Conformance Guide (the ''Guide,'' available at *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm*), which contains technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format. In section 2.2 of the Guide, FDA recommends that each submitted study contain a Study Data Reviewer's Guide containing any special considerations or directions that may facilitate review of the study data. FDA notes in the Guide that the PhUSE SDRG template is an example of how to create an SDRG but does not specifically recommend its use. Although the Guide does not specify specific SDRGs for clinical and nonclinical studies, PhUSE project groups have created separate clinical and nonclinical studies templates. This notice applies specifically to the nonclinical SDRG template. A separate notice was issued for the clinical SDRG template in July 2015 (see ''Intent to Review a Study Data Reviewer's Guide Template'' (80 FR 43779, July 23, 2015)).

FDA now intends to review the PhUSE Nonclinical SDRG template, a deliverable of the working group effort described previously in this document, with the potential result that FDA could recommend the use of the template in its current form, or in a modified form, for use in the regulatory submission of study data in conformance with the Guide. FDA invites public comment on all matters regarding the use of the PhUSE Nonclinical SDRG template.

II. Electronic Access

The PhUSE Nonclinical SDRG template is available at *http://www.phusewiki.org/wiki/index.php?title=Study_Data_Reviewer's_Guide.*

Dated: February 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04791 Filed 3–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3287]

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 of availability.

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 April 4, 2016.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250) amends the Federal Food, Drug, and Cosmetic Act, to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2015 (80 FR 46033), announcing fees for fiscal year (FY) 2016. 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 2016 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 2016 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: (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.

Both Forms FDA 3602 and FDA 3602A are available in the guidance document, ''FY 2016 Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments'' available on the Internet at: *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.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 2016.

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 September 17, 2015 (80 FR 55854), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—FY 2016 MDUFA Small Business Qualification and Certification For a Business Headquartered in the United States	3,600	1	3,600	1	3,600
FDA 3602A—FY 2016 MDUFA Foreign Small Business Qualification and Certification For a Business Headquartered Outside the United States	1,400	1	1,400	1	1,400
Total					5,000

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

Dated: February 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04704 Filed 3–3–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0435]

Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization.'' This draft guidance addresses the inclusion of a boxed warning and a patient decision checklist in the product labeling for permanent hysteroscopically-placed tubal implants intended for female sterilization and as well as the content and format of those materials. This draft guidance is being issued in response to information provided to FDA, including in comments made at a 2015 Panel meeting and in comments submitted to the associated public docket, that women are not receiving or understanding information relating to the risks and benefits of this type of device. This draft