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]

BILLING CODE 4164–01–P

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

guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0435 for ''Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 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.

Submit written requests for a single copies of the guidance to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jason Roberts, Division of Reproductive, Gastro-Renal, and Urological Devices, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993–0002, 240–402–6400.

SUPPLEMENTARY INFORMATION:

I. Background

Female sterilization is a commonly performed surgical procedure that permanently prevents a woman from becoming pregnant by occluding her fallopian tubes. Traditionally, surgery has been performed by bilateral tubal ligation (BTL) through a laparotomy, a mini-laparotomy, transvaginal approach or at the time of cesarean delivery, and, more recently, laparoscopy. During BTL, the fallopian tubes are cut or physically occluded by using various procedures or medical instruments, such as electrosurgical coagulation, implantable clips, or rings. On November 4, 2002, FDA approved the Essure System for Permanent Birth Control, the first permanent hysteroscopically-placed tubal implant, as an alternative, non-incisional method of providing female sterilization. As the number of hysteroscopic sterilizations with such devices has increased, additional information, including reports of adverse events, has accumulated. Some of these events have resulted in surgery and/or removal of the implants.

The **Federal Register** on July 22, 2015 (80 FR 43440), announced a meeting of a public advisory committee of the FDA to seek expert scientific and clinical opinion on the risks and benefits of the Essure System for Permanent Birth Control. On September 24, 2015, FDA convened its Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to discuss available data regarding benefits, risks, and potential mitigation strategies to prevent or reduce the frequency/severity of the adverse events reported in association with this device (Ref. 1). FDA is issuing this draft guidance document after considering the input of the Panel members and other stakeholders. FDA believes that the labeling described in this guidance will help to ensure that women are receiving and understanding information about the risks and benefits of these devices so that they can make informed decisions regarding use of these devices. In addition to issuing this guidance, FDA continues to determine what, if any, further actions are warranted in response to these reported adverse events.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500051 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Meeting Materials of the Obstetrics and Gynecology Devices Panel (2015), available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm463457.htm.*

Dated: February 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04790 Filed 3–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Announcement of Requirements and Registration for the Opioid Overdose Prevention Challenge

Authority: 15 U.S.C. 3719.

AGENCY: SAMHSA, HHS.

ACTION: Notice.

SUMMARY: In summarizing the challenge that will be issued by your agency, please answer the following four questions:

(1) What action is being taken?

The Substance Abuse and Mental Health Services Administration (SAMHSA) has issued a challenge to developers to help support patients in recovery who are receiving medication assisted treatment for opioid use disorder with an innovative app that provides features and information that support their recovery.

(2) Why is this action necessary?

Addressing the opioid epidemic is a top priority for the U.S. Department of Health and Human Services and the Secretary is committed to evidence-informed interventions to turn the tide against opioid drug-related overdose and misuse. To that end, Substance Abuse and Mental Health Services Administration (SAMHSA) is issuing a three-month challenge to spur developers to create an app that provides additional recovery support to patients receiving outpatient medication-assisted treatment for opioid use disorder.

(3) What is the objective of the challenge?

To provide support to people in recovery from opioid use disorder receiving medication assisted-treatment so that they can maintain treatment and achieve long-term recovery.

(4) What is the intended effect of this action?

An increase in the number of individuals with opioid use disorders maintaining recovery; and a reduction in the number of deaths from opioid overdose.

DATES: The challenge starts on March 4, 2016 10:00 a.m. ET. The challenge ends on May 27, 2016 11:59 p.m. ET.

FOR FURTHER INFORMATION CONTACT: Danielle Tarino Rivkin, Health Information Technology Team, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, Public Health Advisor, SAMHSA/CSAT, 5600 Fishers Lane, Rockville, MD 20857, Phone: 240.276.2857, Email: *Danielle.Tarino@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition: Opioid Recovery Support.

Eligibility Rules for Participating in the Competition

To satisfy the mandatory provisions of the COMPETES Act, use the following language:

A. The Competition is open only to:

(i) Individuals who are at least 18 years of age at the time of entry, and are citizens or permanent residents of the United States as of the time of entry;

(ii) teams of eligible individuals where each team member meets the eligibility requirements for individual Contestants; and

(iii) corporations (including not-for-profit corporations and other nonprofit organizations), limited liability companies, partnerships, and other legal entities that, at the time of entry, are domiciled (or incorporated) in the United States, have been duly organized or incorporated and validly exist, and employ no more than one hundred (100) people (''Organizations'').

B. Each team or Organization shall appoint one individual (the ''Representative'') to represent and act, including entering a Submission, on behalf of said team or Organization. The Representative must meet the eligibility requirements for an individual Contestant and must be duly authorized to submit on behalf of the team or Organization. The Representative represents and warrants that: (i) He/she is duly authorized to act on behalf of the team or Organization; and (ii) each member of the team (or in the case of Organization, each participating member) has read the Official Rules and agrees to abide by these Official Rules. The Representative will ensure that each member of the team or Organization reads, agrees to, and complies with the Official Rules.