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; 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 guidance entitled "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization." This guidance addresses the inclusion of a boxed warning and patient decision checklist in the product labeling for permanent hysteroscopically placed tubal implants intended for female sterilization, and the content and format of those materials. FDA believes that the labeling described in this guidance will help to ensure that a woman receives and understands information regarding the benefits and risks of this type of device prior to undergoing implantation. FDA considered comments received on the draft guidance and revised the guidance as appropriate.

The guidance identifies the content and format of certain labeling components for permanent, hysteroscopically placed tubal implants that are intended for sterilization. The guidance applies to all devices of this type, regardless of the insert material composition, location of intended implantation, or exact method of delivery.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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, Guidance for Industry and Food and Drug Administration Staff." 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.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, Guidance for Industry and Food and Drug Administration Staff" 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.

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, such surgery has been performed by surgical bilateral tubal ligation (BTL) through a laparotomy, a mini-laparotomy, a transvaginal approach or at the time of cesarean delivery, and, more recently, laparoscopy. During surgical BTL, the fallopian tubes are cut or physically occluded by using various procedures or medical instruments, such as electrosurgical coagulation or 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.

In the Federal Register on July 22, 2015 (80 FR 43440), FDA announced a meeting of a public advisory committee 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).

A draft guidance regarding the labeling for permanent hysteroscopically placed tubal implants intended for sterilization was announced in the Federal Register on March 4, 2016 (81

FR 11577) and made available for public comment. The comment period closed on May 3, 2016. FDA reviewed and considered all public comments received and revised the guidance as appropriate, including revisions to the content and format of a boxed warning and patient decision checklist. FDA intends to require such labeling as part of a premarket approval application (PMA) for hysteroscopically placed tubal implants intended for sterilization (or a PMA supplement for an already marketed device).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 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 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. References

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 is 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: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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