addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Trisha Eustaquio, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1529, Silver Spring, MD 20993–0002, 301–796–5214.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to recommend the addition of a specific safety statement to the product labeling of certain ultrasonic surgical aspirator devices. This guidance applies to ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery, as such surgeries can include gynecologic procedures. Ultrasonic surgical aspirator devices are surgical tools intended to fragment, emulsify, and aspirate hard and soft tissue. However, the mechanism of action of ultrasonic surgical aspirator devices creates the potential for tissue dissemination. In light of this risk, FDA is providing a specific labeling recommendation in this guidance regarding use of these devices in the removal of uterine fibroids.

FDA is aware that ultrasonic surgical aspirator devices are sometimes used to treat advanced malignancy through cytoreduction (also known as debulking). When used in advanced cancers, the risk of adverse clinical effects from tissue dissemination may be small compared to the device's potential benefits. In certain clinical circumstances, however, the unintended dissemination of cancerous cells may have a significant adverse effect that outweighs any demonstrated benefits. Specifically, use of an ultrasonic surgical aspirator device during treatment for symptomatic uterine fibroids on a woman with an occult uterine sarcoma could result in dissemination of this cancer. Therefore, FDA recommends that manufacturers of ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery prominently include a specific contraindication in their product labeling that the device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

In the **Federal Register** on November 10, 2016 (81 FR 79028), FDA announced the availability of the draft guidance and interested parties were invited to comment by January 9, 2017. FDA has considered all of the public comments received prior to finalizing this guidance.

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 ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices.'' 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. This guidance is not subject to Executive Order 12866.

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 *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500072 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 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: October 25, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23520 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5925]

Standard Development Organizations Whose Susceptibility Test Interpretive Criteria Standards May Be Recognized by the Food and Drug Administration; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is requesting information to assist in identifying standard development organizations (SDOs) that meet the requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act), of the 21st Century Cures Act (Cures Act), which was signed into law on December 13, 2016.

DATES: Submit either electronic or written comments on the notice by November 29, 2017.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 29, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 29, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2017–N–5925 for ''Standard Development Organizations Whose Susceptibility Test Interpretive Criteria Standards May Be Recognized by FDA; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182 or *Katherine.Schumann@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial susceptibility testing is used to determine if certain microorganisms that are isolated from a patient with an infection are likely to be killed or inhibited by a particular antimicrobial drug at the concentrations of the drug that are attainable at the site of infection. Historically, susceptibility test interpretive criteria has been contained in the Microbiology subsection of antimicrobial drug labeling, and there have been significant challenges associated with ensuring that this information is up-to-date for individual antimicrobial drug labels. For some time, FDA and other stakeholders have recognized that susceptibility test interpretive criteria standards established by nationally or internationally recognized SDOs can be useful sources of information to identify and update susceptibility test interpretive criteria.

Section 511A of the FD&C Act (21 U.S.C. 360a) was added by section 3044 of the Cures Act (Pub. L. 114–255), which was signed into law on December 13, 2016. This provision clarifies FDA's authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards established by SDOs. It also clarifies that sponsors of antimicrobial susceptibility testing devices may rely upon listed susceptibility test interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which provides for a more streamlined process for incorporating up-to-date information into such devices.

Section 511A of the FD&C Act requires FDA to establish within 1 year after the date of enactment of the Cures Act an interpretive criteria Web site containing a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. The list of standards consists of new or updated susceptibility test interpretive criteria standards with respect to legally marketed antimicrobial drugs that have been: (1) Established by nationally or internationally recognized SDOs that meet the requirements under section 511A(b)(2)(A)(i) of the FD&C Act and (2) recognized, in whole or in part, by FDA, pursuant to section 511A(c) of the FD&C Act.

Section 511A(b)(2)(A)(i) of the FD&C Act requires that in order for FDA to recognize, in whole or in part, new or updated susceptibility test interpretive criteria standards established by an SDO, the SDO must: (1) Be a nationally or internationally recognized SDO that establishes and maintains procedures to address potential conflicts of interest and ensure transparent decision making; (2) hold meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decision making; and (3) permit its standards to be made publicly available, through the National Library of Medicine or a similar source acceptable to the Secretary of Health and Human Services.

II. Issues for Consideration and Request for Information

FDA is currently identifying SDOs that meet the requirements under section 511A(b)(2)(A)(i) of the FD&C Act and invites submission of information relevant to this task. FDA is particularly interested in publicly available information illustrating how an SDO has national or international recognition, information illustrating an SDO's established and maintained procedures on how the SDO addresses potential conflicts of interest and ensures transparent decision-making, information illustrating that an SDO holds open meetings and has established and maintained processes to ensure that public input by interested parties is considered in decision-making, and information illustrating that an SDO's standards are made publicly available through the National

Institutes of Health/National Library of Medicine or a similar source. When providing this information, please provide weblinks to where this information is publicly available. This information may assist in FDA's determination of which SDOs may fulfill the statutory requirements.

Dated: October 25, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23519 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0334]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for electronic submission of postmarketing safety reports for human drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 29, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 29, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 29, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2008–N–0334 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an