implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in NDAs, ANDAs, BLAs, and INDs to CBER or CDER by specifying the format for electronic submissions. This provision required that the electronic format for submission of applications be specified in guidance and effective no sooner than 24 months after issuance of the final guidance. The initial timetable for the implementation of electronic submission requirements for study data is December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports and requires MedDRA for the coding of adverse events in studies submitted to FDA's CBER or CDER in NDAs, ANDAs, BLAs, and INDs in the electronic common technical document (eCTD) format. However, the requirement to code adverse events using MedDRA in the most current version (available at *https://www.meddra.org*) does not apply to postmarketing studies that are submitted in eCTD sections 5.3.5.4 and 5.3.6 (*https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163175.pdf*).

Generally, the studies included in a submission are conducted over many years and may have used different MedDRA versions to code adverse events. The expectation is that sponsors or applicants will use the most current version of MedDRA at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support and requirement to use the most current version of MedDRA is March 15, 2018. Although the use of the most current version is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the use of the most current version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the ''date requirement begins.'' The Study Data Technical Conformance Guide provides additional information and recommendations on the coding of adverse events (*https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf*).

FDA will no longer support version 8 or earlier of MedDRA. FDA support for earlier versions of MedDRA will end for studies that start after March 15, 2019. The FDA Data Standards Catalog will be updated to list March 15, 2019, as the ''date support ends.'' Studies that start after March 15, 2019, will be required to use the most current version of MedDRA.

Dated: August 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–18471 Filed 8–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–4764]

Policy Clarification and Premarket Notification (510(k)) Submissions for Ultrasonic Diathermy Devices; 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 ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices—Draft Guidance for Industry and Food and Drug Administration Staff.'' When final, this draft guidance will clarify FDA's policy related to compliance with applicable performance standards and conformance to International Electrotechnical Commission (IEC) consensus standards for ultrasonic diathermy devices. This draft guidance will also provide recommendations for information to provide in 510(k) submissions for ultrasonic diathermy devices. 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 October 30, 2017.

ADDRESSES: You may submit comments as follows:

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–D–4764 for ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices—Draft Guidance for Industry and Food and Drug Administration.'' Received comments 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 Office 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.

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 draft guidance document entitled ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices—Draft 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: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993–0002, 301–796–6424.

SUPPLEMENTARY INFORMATION:

I. Background

Ultrasonic diathermy devices are class II medical devices regulated under 21 CFR 890.5300(a), *Ultrasonic diathermy.* Ultrasonic therapy devices must also comply with FDA radiation safety performance standards in 21 CFR part 1010, *Performance standards for electronic products: General,* and 21 CFR 1050.10, *Ultrasonic therapy products.* FDA recognizes that there are several IEC standards with which other countries require conformance or recognize for ultrasonic therapy products. This means that manufacturers, who distribute these products in both the United States and other countries, might have to ensure conformance of their products to IEC standards and comply with FDA performance standards. This may cause manufacturers to duplicate their efforts.

When final, this draft guidance will clarify FDA's policy related to compliance with applicable performance standards and conformance to IEC consensus standards for ultrasonic diathermy devices. If firms provide a declaration of conformity with the relevant provisions of the current FDA recognized versions of the IEC 60601–2–5 and IEC 61689 standards, FDA does not intend to consider whether firms comply with certain requirements of 21 CFR 1050.10. This draft guidance will also provide recommendations for information to provide in 510(k) submissions for ultrasonic diathermy devices.

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 policy clarification and premarket notification (510(k)) submissions for ultrasonic diathermy 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 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 *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices—Draft Guidance for Industry and Food and Drug Administration'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500003 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance also 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; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 1002 through 1050 are approved under OMB control number 0910–0025.

Dated: August 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–18470 Filed 8–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2153]

Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices; 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 ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.'' FDA is issuing this guidance to clarify how we evaluate real-world data to determine whether it may be sufficiently relevant and reliable to generate the types of real-world evidence that can be used in FDA