4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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 a draft document entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device investigational device exemption (IDE) applications, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, evaluation of automatic class III designations (de novo requests), premarket notification (510(k)) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application, Accessory Classification Requests, and certain investigational new drug (IND) applications and biologics license applications (BLAs). This draft guidance, when finalized, is intended to supersede the document entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug

Administration Staff" issued on September 29, 2017. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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-2018-D-1774 for "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; 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 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: J. Allen Hill, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5627, Silver Spring, MD 20993-0002, 301-796-7086; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The pre-IDE program was established in 1995, to provide applicants a mechanism to obtain FDA feedback on future IDE applications prior to their submission. Over time, the pre-IDE program evolved to include feedback on PMA applications, HDE applications, de novo requests, and 510(k) submissions, as well as to address whether a clinical study requires submission of an IDE.

To capture this evolution, the Secretary of Health and Human Services' 2012 Commitment Letter to Congress regarding the Medical Device User Fee Amendments of 2012 (MDUFA III) included FDA's commitment to institute a structured process for managing these interactions, referring to them as "Pre-Submissions." The Pre-Submission Guidance, published February 18, 2014, implemented the broader Q-Submission (Q-Sub) Program, which includes Pre-Submissions (Pre-Subs), as well as additional opportunities to engage with FDA.

As part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), industry and the Agency agreed to refine the Q-Sub Program with changes related to the scheduling of

Pre-Sub meetings and a new performance goal on the timing of FDA feedback on Pre-Subs. This guidance reflects those changes and clarifies other elements of the Q-Sub program.

This draft guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device IDE applications, PMA applications, HDE applications, de novo requests, 510(k) Submissions, CLIA Waiver by Application, Accessory Classification Requests, and certain INDs and BLAs.

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 "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff." 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 https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This draft guidance is also available at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or https://www.regulations.gov. Persons unable to download an electronic copy of

"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft 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 1677 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved information collections 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 803 are approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 are approved under OMB control number 0910-0231; and the collections of information for "Request for Feedback on Medical Device Submissions" are approved under OMB control number 0910-0756.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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