4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0147]

Draft Guidance for Industry and Food and Drug Administration Staff; Types of Communication During the Review of Medical Device Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Types of Communication During the Review of Medical Device Submissions." The purpose of this guidance is to update the Agency's approach to Interactive Review to reflect FDA's implementation of the Medical Device User Fee Act of 2007 (MDUFA II) Commitment Letters and of undertakings agreed in connection with the Medical Device User Fee Amendments of 2012 (MDUFA III) and to incorporate additional types of communication, all of which increase the efficiency of the review process. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Types of Communication During the Review of Medical Device Submissions"

to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the letters dated September 27, 2007, from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Chairman of the Committee on Energy and Commerce of the U.S. House of Representatives setting out the goals of section 201(c) of MDUFA II, Title II of the Food and Drug Administration Amendments of 2007 (FDAAA) (21 U.S.C. 379i note), FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. Further, during discussions with representatives of the medical device industry in the development of the Agency's recommendations for MDUFA III, Title II of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144 (July 9, 2012), 126 Stat. 1002 (21 U.S.C. 301 note), the Agency proposed process improvements to provide further transparency into the review process, including new communication commitments.

This guidance describes four types of communication that occur during the review of a medical device premarket submission. The four types of communication are:

Acceptance Review Communication, Substantive Interaction, Interactive Review, and Missed MDUFA Decision Communication.

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 Agency's current thinking on communication during a medical device premarket submission review to provide further transparency into, and to increase the efficiency of, the review process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov. To receive "Types of Communication During the Review of Medical Device Submissions," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1804 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; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-05015 Filed 03/04/2013 at 8:45 am; Publication Date: 03/05/2013]