This document is scheduled to be published in the
Federal Register on 04/04/2014 and available online at
http://federalregister.gov/a/2014-07546, and on **FDsys.gov**

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 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 and other additional types of communication, to reflect FDA's implementation of the Medical Device User Fee Act of 2007 (MDUFA II) Commitment Letters and of undertakings agreed to in connection with the Medical Device User Fee Amendments of 2012 (MDUFA III). These new Agency communication commitments are to increase the efficiency of the review process.

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: 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 single copies of the guidance document entitled "Types of Communication During the Review of Medical Device Submissions" 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 (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and 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 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: Samie Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1533, Silver Spring, MD 20993-0002, 301-796-6055, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

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) (21 U.S.C. 301 note), the Agency proposed process improvements to provide further transparency into the review process, including new communication commitments.

In the Federal Register on March 5, 2013 (78 FR 14305), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by June 3, 2013. Four comments were received and, in general, were supportive of the guidance. However, the comments contained multiple recommendations pertaining to the content of the guidance and the need for clarification, particularly for the Interactive Review section. In response to these comments, FDA revised the guidance document to restructure the Interactive Review section to clarify how this process works and to include references to additional submission types for which Interactive Review pertains. Although several commenters expressed concern about FDA's intention to limit the last round of Interactive Review to 7 days, we did not modify the guidance because this approach is needed in order to appropriately balance the intent of interactive review with FDA's commitment to meet the performance goals agreed upon as part of MDUFA III. In response to comments regarding our intention to limit the issuance of second Additional Information (AI) letters for 510(k) submissions, the guidance was modified slightly to clarify the circumstances in which a second AI letter might be issued, but remains unchanged in explaining that these circumstances will remain limited and at FDA's discretion. FDA will continually assess any impacts that the limited use of a second AI letter may have, and, if needed, may

consider modifications to this approach. In addition to modifications to the Interactive Review section, we clarified other items throughout the guidance, and included Pre-Submissions as a submission type subject to Acceptance Communication. This document supersedes "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" dated February 28, 2008.

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 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 guidance may do so by using 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 or from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. 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: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-07546 Filed 04/03/2014 at 8:45 am; Publication Date: 04/04/2014]