4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0838]

Procedures for Meetings of the Medical Devices Advisory Committee; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Procedures for Meetings of the Medical Devices Advisory Committee." The Center for Devices and Radiological Health (CDRH) is issuing this guidance to provide additional information regarding the processes for meetings of the Medical Devices Advisory Committee panels other than the Dispute Resolution Panel (DRP). This guidance describes the general circumstances in which CDRH consults with a panel, the process for exchange of information between CDRH, the members of the panel, industry, and the public, and the conduct of panel meetings. This guidance supplements existing FDA Agency-wide guidance on the conduct of Advisory Committee meetings. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 Submit written requests for a single hard copy of the draft guidance document entitled "Procedures for Meetings of the Medical Devices Advisory Committee" to the Office of the Center Director, Guidance and Policy Development,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.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993-0002, 301-796-6313.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is issuing this draft guidance to provide additional information regarding the processes for meetings of the Medical Devices Advisory Committee panels other than the DRP. The term "panel," as used in this guidance, refers to the panels established under the Medical Devices Advisory Committee charter excluding the DRP. This guidance describes the general

circumstances in which CDRH consults with a panel of the Medical Devices Advisory Committee, the process for exchange of information between CDRH, the members of the panel, industry, and the public, and the conduct of panel meetings. The Medical Devices Advisory Committee includes 17 panels other than the DRP (Ref. 1). The panels, according to their specialty area and authorization, advise the Commissioner of Food and Drugs in discharging responsibilities as they relate to assuring the safety and effectiveness of medical devices, and as required, any other product for which FDA has regulatory responsibility.

This draft guidance is intended to provide more comprehensive information for industry and for CDRH staff on the processes associated with a panel meeting held for any of the reasons identified in the guidance. Once final, this guidance will replace the "Guidance on Amended Procedures for Advisory Panel Meetings" (Ref. 2) and the guidance document entitled "Panel Review of Premarket Approval Applications #P91-2 blue book memo" (Ref. 3). This guidance supplements existing FDA Agency-wide guidance on the conduct of Advisory Committee meetings.

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 the panel meeting process for medical devices. 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 downloading an electronic copy from 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 http://www.regulations.gov. Persons unable to download an electronic copy of "Procedures for Meetings of the Medical Devices Advisory Committee" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 413 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 860 have been approved under OMB control number 0910-0138; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332.

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.

VI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. CDRH's Medical Devices Advisory Committee, available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm.

2. "Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings," July 2000, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073726.pdf.

3. "Panel Review of Premarket Approval Applications #P91-2 (blue book memo)," May 1991, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm.

Dated: March 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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