



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6888]

Neurological Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the *Federal Register* of December 28, 2017. The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993-0002, Aden.Asefa@fda.hhs.gov, 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code NE. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 28, 2017, 82 FR 61574, FDA announced that a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee would be held on March 1, 2018, from 8 a.m. to 6 p.m. On page 61574, in the 3rd column, the *Procedure* portion of the document is changed to read as follows:

*Procedure:* FDA will work with affected industry organizations that have an interest in intracranial aneurysm treatment devices and who wish to make a presentation separate from the

general Open Public Hearing; time slots on March 1, 2018, between approximately 9:40 a.m. and 11 a.m. Representatives from industry organizations interested in making formal presentations to the committee should notify the contact person on or before February 16, 2018.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 16, 2018. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 9, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled Open Public Hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 12, 2018.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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