

## **Federal Register: The Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

FDA (The Center for Devices and Radiological Health)

[Federal Register: January 27, 2010 (Volume 75, Number 17)] [Notices] [Page 4407-4408] From the Federal Register Online via GPO Access [[wais.access.gpo.gov](http://wais.access.gpo.gov)] [DOCID:fr27ja10-101] -----

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-N-0001] The Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting AGENCY: Food and Drug Administration, HHS. ACTION: Notice.

----- This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee. General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. Date and Time: The meeting will be held on March 12, 2010, from 8 a.m. to 5 p.m. Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD. Contact Person: Deborah Falls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, or FDA Advisory Committee Information Line, 1- 800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting. Agenda: On March 12, 2010, the committee will discuss, make recommendations, and vote on a premarket approval application for the Deep Brain Stimulation System for Epilepsy sponsored by Medtronic, Inc. This device is indicated as adjunctive therapy for reducing the frequency of seizures in individuals diagnosed with epilepsy. For this device, a patient's epilepsy should be characterized by partial-onset seizures (affecting only a part of the brain when they begin), with or without secondary generalization that are refractory to antiepileptic medications. ``Secondary generalization'' is used to describe a partial-onset seizure that later spreads to the whole brain. ``Refractory'' to antiepileptic medications means that the patient's epilepsy does not respond to approved medications. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> [1]. Scroll down to

the appropriate advisory committee link. Procedure: 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 March 5, 2010. Oral presentations from the public will be scheduled at approximately 1 p.m., immediately following lunch. Those desiring to make 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 25, 2010. 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 26, 2010. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301-796-5966, at least 7 days in advance of the meeting. FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> [2] for procedures on public conduct during advisory committee meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2). Dated: January 19, 2010. Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Programs. [FR Doc. 2010-1519 Filed 1-26-10; 8:45 am] BILLING CODE 4160-01-S

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**Links:**

[1] <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>

[2] <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm>

[3] <http://edocket.access.gpo.gov/2010/2010-1519.htm>