

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM
Display Date 5-10-04
Publication Date 5-11-04
Certifier D. Hawkins

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 June 15, 2004, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, 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.

oc04120

4047

NMI

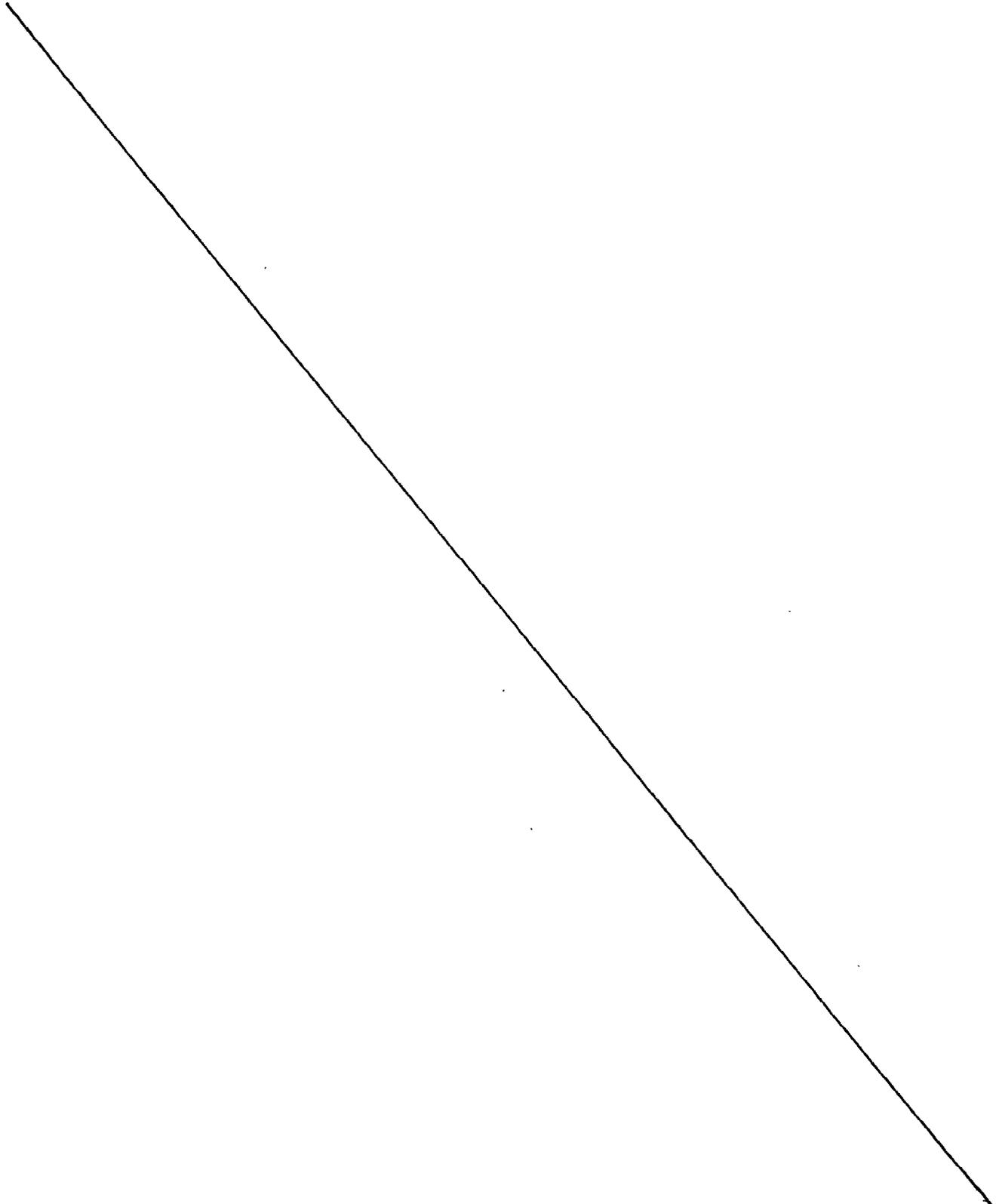
Agenda: The committee will discuss, make recommendations, and vote on premarket approval application supplement for a vagus nerve stimulation therapy system. The system is indicated for the adjunctive long-term treatment of chronic or recurrent depression for patients who are experiencing a major depressive episode that has not had an adequate response to two or more antidepressant treatments. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. The material will be posted on June 14, 2004.

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 by June 1, 2004. Oral presentations from the public will be scheduled for approximately 90 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 1, 2004, 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.

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 Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act

(5 U.S.C. app. 2).

104 Dated: 4/21/04 5/3/04
May 3, 2004.

Peter J. Pitts
Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins