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Display Date	11/1/00
Publication Date	11/6/00
Certifier	mab

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed 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 November 16, 2000, 9:30 a.m. to 7 p.m.

Location: Quality Suites Hotel, Potomac Rooms II and III, Three Research Ct., Rockville, MD.

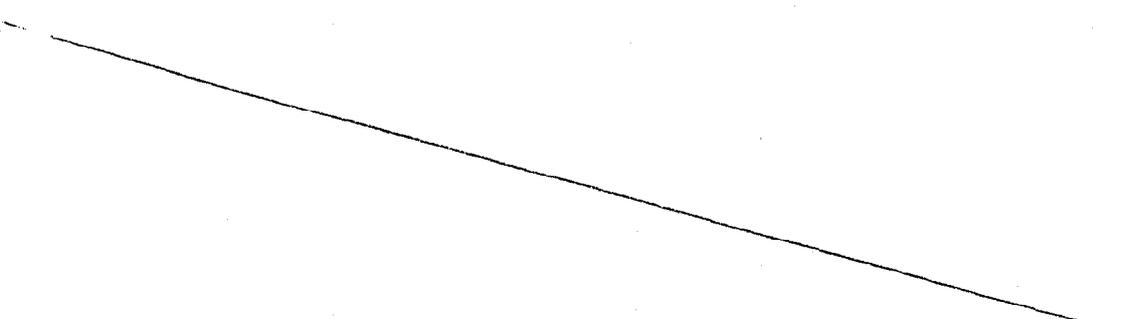
Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12513. Please call the Information Line or access the Internet (http://www.fda.gov/cdrh/panelmtg.html for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on: (1) The design of clinical trials for devices to prevent stroke, to treat stroke, and to provide neurological protection after stroke; and (2) the design of clinical studies for temperature control devices to provide neurological protection.

*Procedure:* On November 16, 2000, from 10 a.m. to 7 p.m., the meeting is open to the public. 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 November 9, 2000. On November 16, 2000, oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. for the discussion of the design of clinical studies for devices to prevent stroke, to treat stroke, and to provide neurological protection after stroke, and between approximately 4:30 p.m. and 5 p.m. for the discussion of the design of clinical studies for temperature control devices to provide neurological protection. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2000, 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.

*Closed Committee Deliberations:* On November 16, 2000, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues and applications.

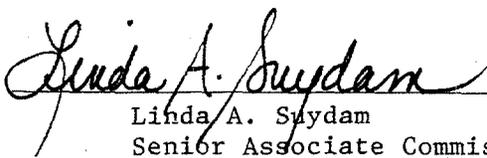
FDA regrets that it was unable to publish this notice 15 days prior to the November 16, 2000, Neurological Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Neurological Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2). 03 31 2000

Dated: \_\_\_\_\_

  
\_\_\_\_\_  
Linda A. Snyder  
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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M. A. Bryant