

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

**Circulatory System 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: Circulatory System 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 April 4, 2000, 8 a.m. to 6 p.m.

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

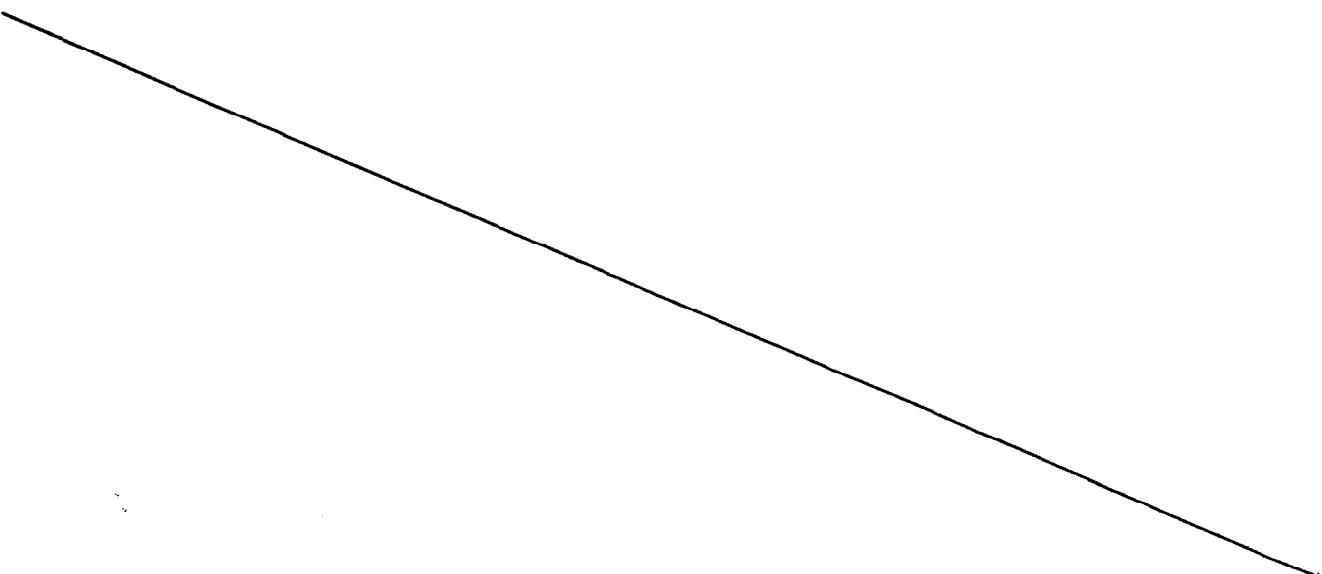
Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: There will be a brief FDA presentation on the least burdensome provisions of the FDA Modernization Act of 1997. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for the following: (1) Devices using spinal cord stimulation in the treatment of angina pectoris; (2) rate-responsive pacemakers, specifically,

the evaluation of rate-adaptive features; and (3) devices used in the treatment of atrial fibrillation. Background information, questions for the panel, and a bibliography for each topic to be discussed by the committee are available to the public on the Internet at <http://www.fda.gov/cdrh/upadvmtg.html>.

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 March 28, 2000. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 28, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the April 4, 2000, Circulatory System Devices Panel of the Medical Device Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel 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).

Dated: March 20, 2000


Linda A. Suydam
Senior Associate Commissioner

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