

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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**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). At least one portion of the meeting will be closed 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 February 5, 2001, from 8 a.m. to 6 p.m.

Location: Gaithersburg Marriott Washingtonian Center Salons F and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, 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.

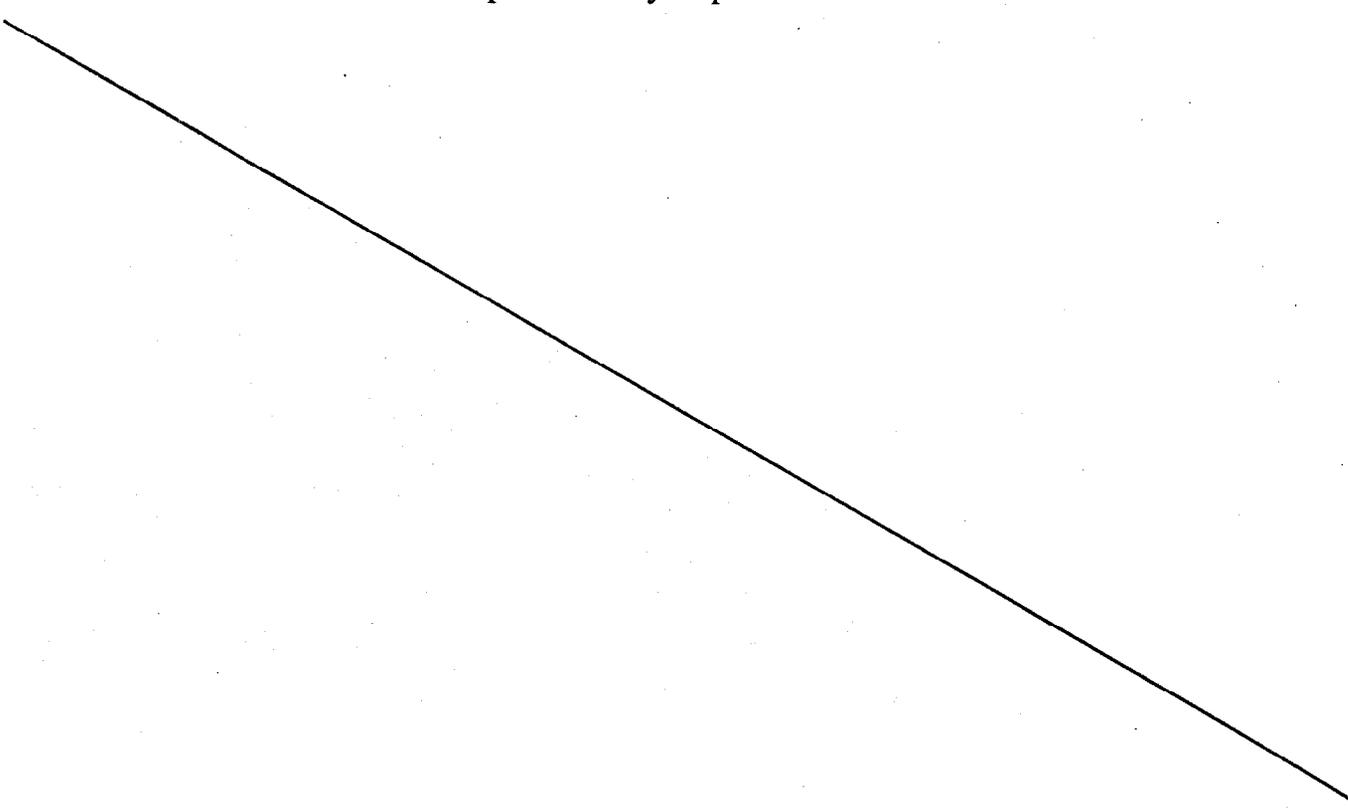
Agenda: The committee will discuss and make recommendations on a premarket submission for a distal protection device used in the treatment of saphenous vein graft disease. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for distal protection devices used in diseased saphenous vein grafts.

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Procedure: On February 5, 2001, from 8 a.m. to 3 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 January 26, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee near the end of the panel deliberations on February 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 26, 2001, 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 February 5, 2001, from 3 p.m. to 6 p.m., the meeting will be closed to the public to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future circulatory system device submissions. In addition, the committee will discuss and review trade secret and/or confidential commercial information presented by a sponsor.



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

2).

Dated: January 12, 2001.

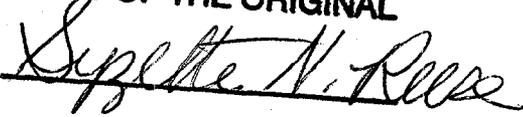


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Supette N. Reese