

DEPARTMENT OF HEALTH & 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.

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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 December 4, 2000, 10 a.m. to 6 p.m., and December 5, 2000, 8 a.m. to 2 p.m.

*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

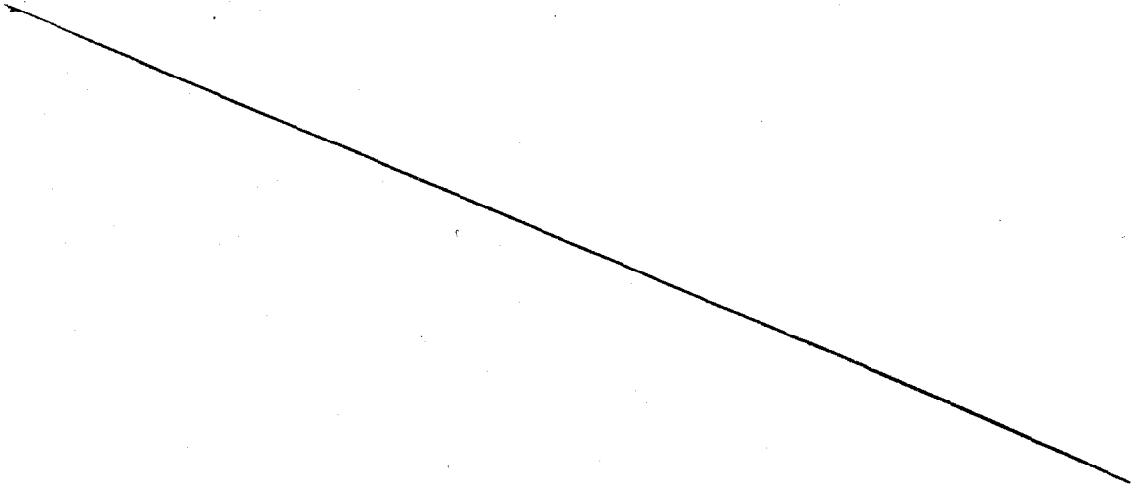
*Contact Person:* Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On December 4, 2000, the committee will discuss and make recommendations on a reclassification petition proposing to down-classify percutaneous transluminal coronary angioplasty (PTCA) catheters from class III to class II. The petition is available for public review and comment on the FDA Dockets Management Branch website at [www.fda.gov/ohrms/dockets](http://www.fda.gov/ohrms/dockets)

and is listed as docket number 00P-1533. In the context of the reclassification petition, the committee will be asked to consider possible modifications to the draft guidance document entitled "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents" (May 1995). The guidance document can be viewed on the FDA website at [www.fda.gov/cdrh/ode/846.pdf](http://www.fda.gov/cdrh/ode/846.pdf). Questions for the committee regarding the December 4, 2000, session can be found on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

On December 5, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application for an implantable cardioverter defibrillator used in the treatment of atrial fibrillation.

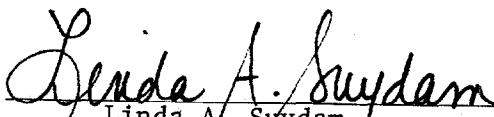
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 27, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and near the end of the committee deliberations on December 4, 2000; and between approximately 8 a.m. and 8:30 a.m., and near the end of the committee deliberations on December 5, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 27, 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.



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

2).

Dated: 11/15/00  
November 15, 2000

  
Linda A. Suydam,  
Senior Associate Commissioner.

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

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