

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date:	2-5-02
Publication:	2-6-02
Certifier:	R. LEDESMA

**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 March 4, 2002, from 10 a.m. to 5 p.m., and on March 5, 2002, from 8 a.m. to 3 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact: Lesley L. Ewing, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 161, 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 March 4, 2002, the committee will discuss, make recommendations, and vote on a supplement to a premarket approval application (PMA) for a left ventricular assist device to be used as destination therapy in patients with end stage congestive heart failure. On March 5, 2002, the committee will discuss, make recommendations, and vote on a PMA for an implantable

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pacemaker/defibrillator used for treatment of both congestive heart failure and life threatening dysrhythmias. Background information for each day's 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>. Material for the March 4 session will be posted on March 1, 2002; material for the March 5 session will be posted on March 4, 2002.

Procedure: On March 4, 2002, from 10 a.m. to 4 p.m., and on March 5, 2002, 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 February 21, 2002. On both days, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of each topic and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 21, 2002, 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 AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Closed Committee Deliberations: On March 4, 2002, from 4 p.m. to 5 p.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

2).

Dated: 1-30-02
January 30, 2002.

Linda A. Szydram
Linda A. Szydram,
Senior Associate Commissioner.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
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Regina Adams