DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 March 17 and 18, 2004, from 9 a.m. to 5 p.m.

Location: Hilton Washington D.C. North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

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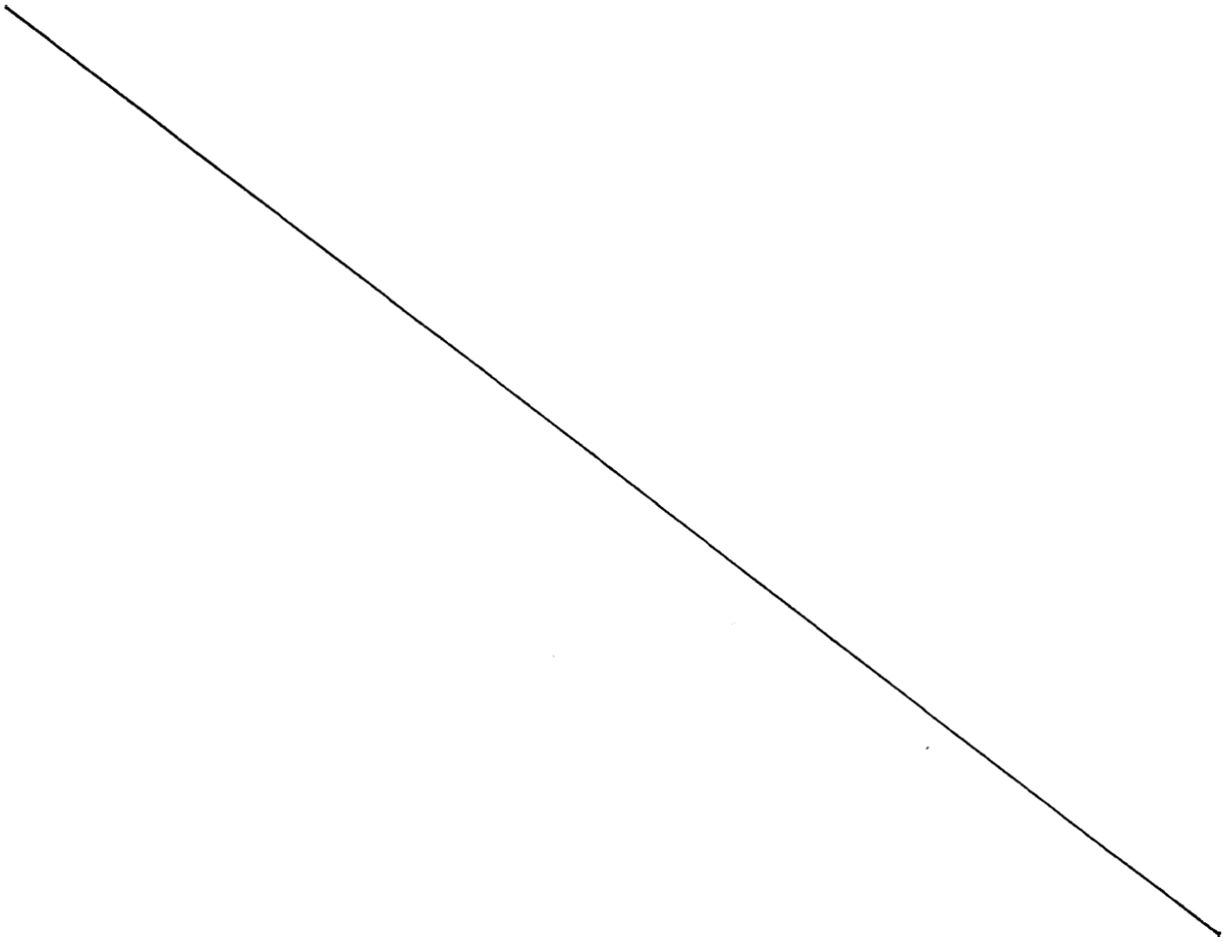
Agenda: On March 17, 2004, the committee will discuss, make recommendations, and vote on a premarket approval application for a Total Artificial Heart indicated for bridge to transplant usage in cardiac transplant-eligible candidates at **risk** of imminent death from non-reversible biventricular failure and replaces the patient's native ventricles and valves. The device is intended for use inside the hospital. On March 18, 2004, FDA will present to the committee the history, current medical practice, and regulatory background regarding Aortic Anastomotic Devices. The committee will discuss and make recommendations regarding the type of data and study required to effectively evaluate performance of Aortic Anastomotic Devices for marketing, recognizing the significant public health impact on cardiac disease they represent. Background information for the day's topics, 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 17, 2004, session will be posted on March 16, 2004; material for the March 18, 2004, session will be posted on March 17, 2004.

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 8, 2004. On March 17, 2004, oral presentations from the public will be scheduled for approximately **30** minutes at both the beginning and near the end of committee deliberations. On March 18, 2004, oral presentations from the public will be scheduled from approximately 10 a.m. to 12:30 p.m. and for approximately **30** minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations

should notify the contact person before March 8, 2004, 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.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 2/19/04

February 19, *2004.*

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04–????? Filed ??–??–04;8:45 am]

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