

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.

Immediate Display
DMB
Display Date 10-11-02 @ 4:26pm
Publication Date 10-17-02
Certifier D. Hawkins

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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 October 22, 2002, from 10 a.m. to 5:30 p.m., and October 23, 2002, from 8:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., 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 12625. Please call the Information Line for up-to-date information on this meeting.

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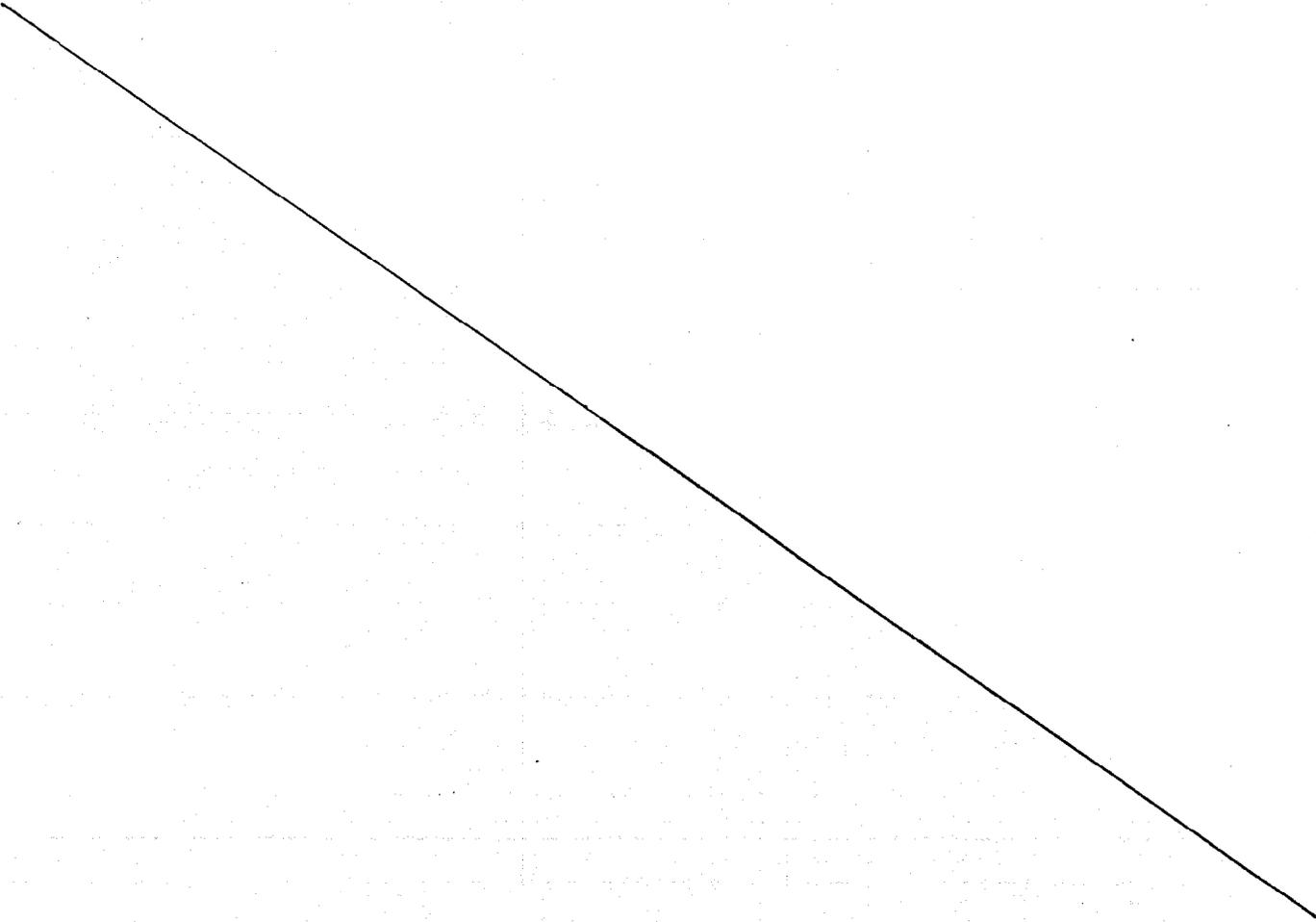
Agenda: On October 22, 2002, the committee will discuss, make recommendations, and vote on a premarket approval application for a drug-coated coronary artery stent intended to treat coronary artery obstructions and to help prevent in-stent stenosis. On October 23, 2002, the committee will discuss and make recommendations on a premarket notification (510(k)) submission for an arterial cannula intended to prevent an adverse neurological or limb threatening event. Background information for each day's topic, including the agenda and questions for the committee, will be available to the public one business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the October 22, 2002, session will be posted on October 21, 2002; material for the October 23, 2002, session will be posted on October 22, 2002.

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 October 18, 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 October 18, 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, as soon as possible.

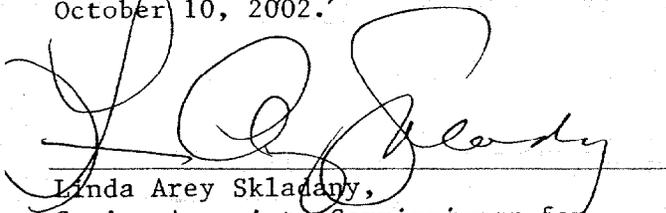
FDA regrets that it was unable to publish this notice 15 days prior to the October 22, 2002, Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee 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: 10/10/2002
October 10, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for
External Relations.

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

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Dawn P. Hawkins