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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	J. M. Underwood

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.

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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 June 19, 2000, 10 a.m. to 6 p.m. and on June 20, 2000, 10 a.m. to 4 p.m.

*Location:* Hilton, Salons A, B, and C, 620 Perry Pkwy., 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 June 19, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application for an intravascular radiation device used in the treatment of instent restenosis. On June 20, 2000, the committee will discuss a modification to the guidance document entitled "Draft Guidance for Implantable Cardioverter-Defibrillators." Specifically, the

modification would allow general indications for use for implantable cardioverter defibrillators. The draft guidance, version 4.3, issued June 24, 1996, is available to the public on the Internet at <http://www.fda.gov/cdrh/ode/965.html>. Background information, questions for the panel, and a bibliography for this topic will be available to the public on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

*Procedure:* On June 19, 2000, from 10 a.m. to 6 p.m. and on June 20, 2000, from 10 a.m. to 4 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 June 15, 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 panel deliberations on June 19, 2000, and between approximately 10 a.m. and 10:30 a.m., and near the end of the panel deliberations on June 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 12, 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.

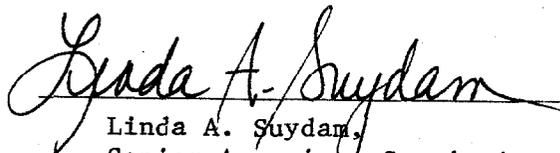
*Closed Committee Deliberations:* On June 20, 2000, from 8 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the 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: 6-9-00

  
Linda A. Suydam,  
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



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