

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

April 23, 2001

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Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, Maryland

9:00 – 1:00	PMA Discussion, Recommendations, and Voting	
9:00 a.m.	Call to Order	Cynthia Tracy, M.D., Chairperson
9:05 – 9:15 a.m.*	First Open Public Hearing*	
9:15 – 10:15 a.m.	Sponsor Presentation: Sulzer IntraTherapeutics, Inc. P000033, IntraCoil Self-Expanding Peripheral Stent Maria Brittle, Regulatory Affairs Manager, Sulzer IntraTherapeutics Kenneth Rosenfield, M.D., St. Elizabeth's Medical School Tufts University School of Medicine Gary Ansel, M.D., Grant/Riverside Methodist Hospitals Medical College of Ohio	
10:15 – 10:30 a.m.	FDA Presentation Judith Danielson, lead reviewer, FDA Paul Chandeysson, M.D., clinical reviewer, FDA	
10:30 a.m.	Open Committee Discussion, Recommendations, and Voting	Cynthia Tracy, M.D.
1:00 p.m.	Adjourn – Break for Lunch	
2:00 – 5:00 p.m.	Clinical Study Design Issues for Iliac Stenting	
2:00 p.m.	Call to Order	Cynthia Tracy, M.D.
2:00 – 2:15 p.m.	FDA Presentation: Questions for the Panel Judith Danielson Food and Drug Administration	
2:15 – 3:15 p.m.** (approx. time)	Second Open Public Hearing**	
3:15 p.m.	Open Committee Discussion	
5:00 p.m.	Adjourn	

FIRST OPEN PUBLIC HEARING*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. This Open Public Hearing will be kept short in order to allow sufficient time in the afternoon for scheduled speakers.

SECOND OPEN PUBLIC HEARING**

In the afternoon, after the FDA introduction to the discussion on Clinical Trial Issues, an open public session will be conducted for interested persons to address issues specific to the matter before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Tracy will recognize unscheduled speakers as time allows.

The following people have requested time to speak:

- Gary Ansel, Grant/Riverside Methodis Hospitals / Medical College of Ohio
- Christopher White,
- Mark Burket,
- Kenneth Rosenfield, St. Elizabeth's Medical Center / Tufts University School of Medicine
- Brian Stanken, M.D., University of Maryland Medical System, SCVIR Executive Council Member

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.