

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	8-24-01
Publication Date	8-27-01
Certifier	SKREESE

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 September 10, 2001, from 9 a.m. to 6 p.m., and September 11, 2001, from 8 a.m. to 6 p.m.

Location: Marriott Hotel, Salons D, E, and F, 9751 Washingtonian Blvd., Gaithersburg, MD.

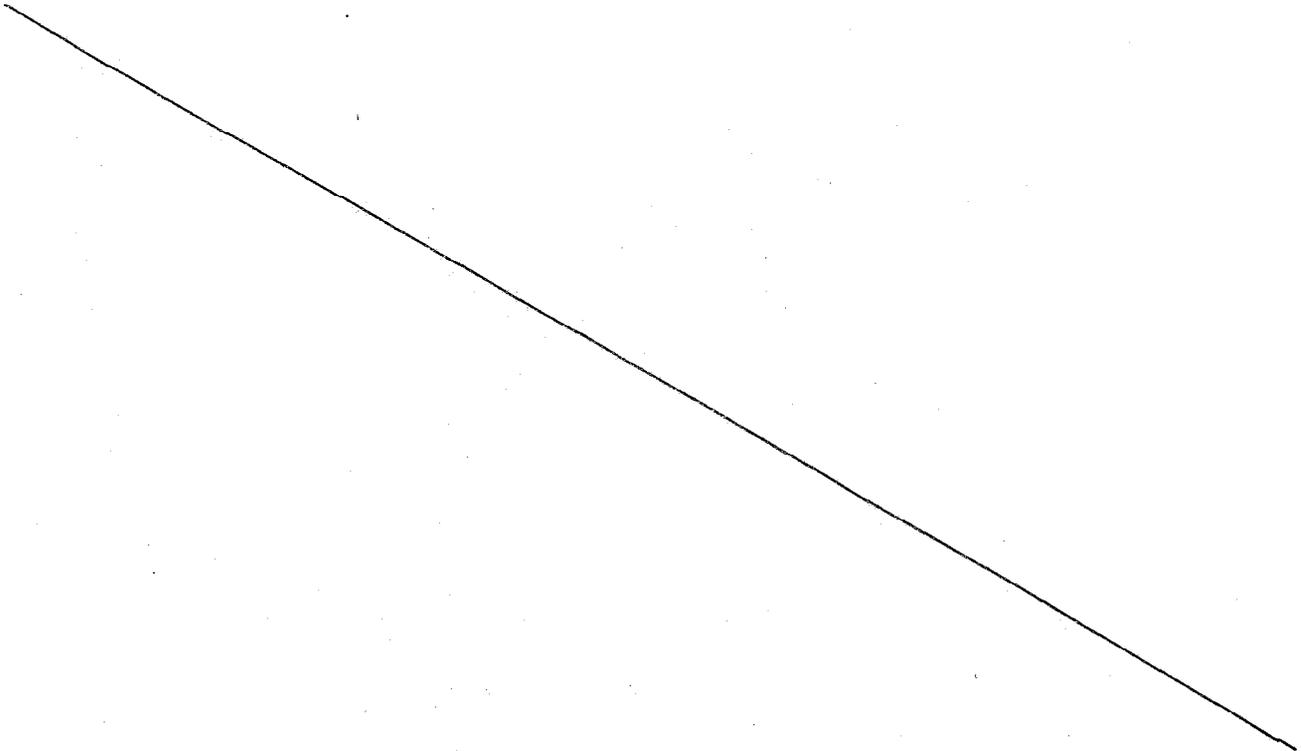
Contact: Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 10, 2001, the committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for septal occluders. On September 11, 2001, the committee will discuss, make recommendations, and vote on two PMAs, one for a surgical sealant and one for a biological glue. 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 September 10, 2001, meeting will be posted on September 7, 2001; material for the September 11, 2001, meeting will be posted on September 10, 2001.

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 August 31, 2001. 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 August 31, 2001, 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.

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



Dated: 8/20/01
August 20, 2001

Linda A. Snydam
Linda A. Snydam
Senior Associate Commissioner

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Suzette W. Rose