

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. VEDESMA

Food and Drug Administration

Obstetrics and Gynecology 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). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology 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 9, 2003, from 12:30 p.m. to 5 p.m. and June 10, 2003, from 8:30 a.m. to 4:30 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Joyce M. Whang, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 9, 2003, the committee will hear a presentation on post-approval studies and adverse events related to an intrapartum fetal pulse

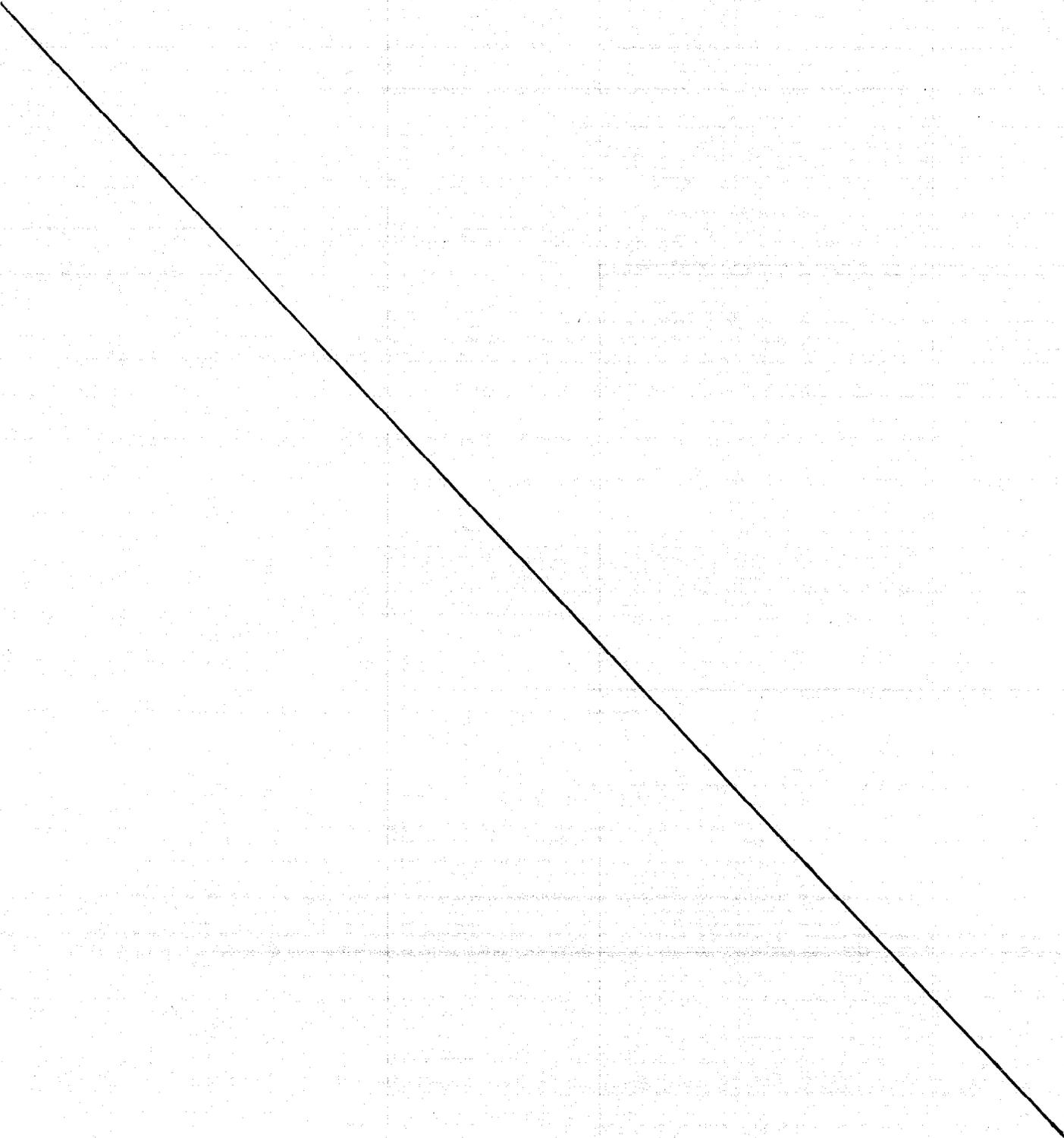
oximeter. On June 10, 2003, the committee will discuss, make recommendations, and vote on a premarket approval application for an endometrial ablation device. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the June 9, 2003, session will be posted on June 6, 2003. Material for the June 10, 2003, session will be posted on June 9, 2003.

Procedure: On June 9, 2003, from 2:30 p.m. to 5 p.m. and on June 10, 2003, from 8:30 a.m. to 4:30 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 May 30, 2003. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on June 9, 2003, and between approximately 8:45 a.m. and 9:15 a.m. and 3 p.m. and 3:30 p.m. on June 10, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 30, 2003, 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 9, 2003, from 12:30 p.m. to 2:30 p.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)) presented by a sponsor.

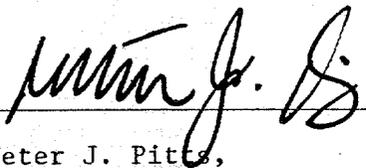
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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: 5/13/03
May 13, 2003.


Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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