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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 January 24, 2000, from 9 a.m. to 6 p.m., and January 25, 2000, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Elisa D. Harvey, 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 (or 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 January 24, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application for a fetal pulse oximeter. On January 25, 2000, the committee will discuss a draft guidance document on adhesion barrier products intended for use in pelvic

and/or abdominal surgery. The draft guidance document is available to the public on the Internet at <http://www.fda.gov/cdrh/ode/resorbable.pdf> and <http://www.fda.gov/cdrh/ode/1356.html>, or by contacting CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111, specify number 1356 when prompted for the document shelf number.

Procedure: On January 24, 2000, from 9 a.m. to 6 p.m., and January 25, 2000, from 9 a.m. to 5 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 January 20, 2000. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and 5 p.m. and 5:30 p.m. on January 24, 2000, and between approximately 9:30 a.m. and 10 a.m. on January 25, 2000. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before January 20, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and address of proposed participants, and an indication of the approximate time requested to make their presentation.

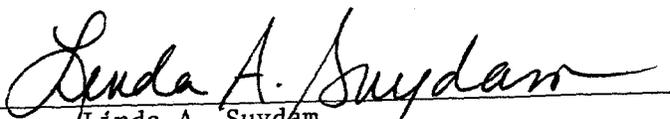
Closed Committee Deliberations: On January 25, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to the public. The committee will hear and review trade secret and/or confidential commercial information on pending and future applications under review. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the January 25, 2000, Obstetrics and Gynecology 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 Obstetrics and Gynecology 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.

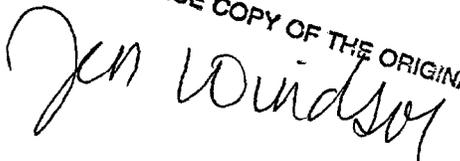
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 1/10/00



Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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