

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 July 22, 2002, from 8:30 a.m. to 5 p.m., and on July 23, 2002, from 8 a.m. to 11 a.m.

Location: DoubleTree Hotel, Plaza I and II, 1750 Rockville Pike, Rockville, MD.

Contact Person: 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 Hotline, 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 July 22, 2002, the committee will hear a presentation on post-market surveillance of vacuum assisted delivery devices. The committee will also discuss, make recommendations, and vote on a premarket approval application for a permanent contraceptive 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 July 22, 2002, session will be posted on July 19, 2002.

Procedure: On July 22, 2002, from 8:30 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 July 11, 2002. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and 3:30 p.m. and 4 p.m. on July 22, 2002. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before July 11, 2002, 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 July 23, 2002, from 8 a.m. to 11 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)) regarding pending and future device issues. In addition, the committee will discuss and review trade secret and/or confidential commercial information 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.

FDA regrets that it was unable to publish this notice 15 days prior to the July 22, 2002, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issue(s) 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: July 2, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S