with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–886 Filed 1–9–98; 2:09 pm]

BILLING CODE 4160–01–F

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 regulatory issues.

Date and Time: The meeting will be held on January 27, 1998, 10:30 a.m. to 5 p.m., and January 28, 1998, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, 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 (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 27, 1998, the Committee will consider issues relating to the study and evaluation of device systems for thermal endometrial ablation. In the context of the current guidance document on thermal endometrial ablation devices, the Committee's discussion will address initial safety studies, as well as the pivotal safety and effectiveness study. This will include inclusion/exclusion criteria, type(s) of control, alternative study endpoints, and length of followup, both premarket and postmarket. Single copies of the guidance document are available to the public by contacting the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or by FAX 301–443–8818, and requesting the document by shelf #547.

Procedure: On January 27, 1998, from 12:30 p.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, 1998. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before January 20, 1998, 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 27, 1998, from 10:30 a.m. to 12:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of secret and/or confidential commercial information on present and future device issues. On January 28, 1998, from 8:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to hear and review trade secret and/or confidential commercial information on a product development protocol.

FDA regrets that it was unable to publish this notice 15 days prior to the January 27 and 28, 1998, 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 meeting were available at this time, the Commissioner 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: January 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–884 Filed 1–9–98; 2:09 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

Use of IEC 60601 Standards; Medical Electrical Equipment; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Use of IEC 60601 Standards; Medical Electrical Equipment.'' The purpose of the draft guidance document is to provide guidance to the Office of Device Evaluation (ODE) reviewers on the use of the International Electrotechnical Commission (IEC) 60601 series of standards, including declarations of conformity to the standards, during the evaluation of premarket submissions for electrical medical devices.

DATES: Written comments concerning this draft guidance must be received by April 13, 1998.

ADDRESSES: Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the draft guidance to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Melvyn R. Altman, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 2094