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

Gaither Rd., Rockville, MD 20850, 301–594–4766 ext. 103.

SUPPLEMENTARY INFORMATION:

I. Background

The IEC 60601 series of international consensus standards addresses many aspects of safety common to electrical medical devices. Some of these safety aspects pertain to mechanical, electric shock, fire, and electromagnetic compatibility. These standards are used worldwide and play a central role in the regulation of medical devices in the European Union, Canada, Australia, and other countries. They have undergone continuous scrutiny and revision with the participation of FDA staff. IEC 60601–1, the basic standard in the series, was first published in 1977 (as IEC 601–1). The second edition of IEC 60601–1 was published in 1988, and was subsequently amended in 1991 and 1995. A U.S. version of IEC 60601–1 (UL2601–1) is presently being balloted to become an American National Standard.

The IEC 60601 series of standards consists of the following:

- A general (base) safety standard, IEC 60601–1;
- Collateral standards, IEC 60601–1–X, covering issues integral to the general standard but that are too expansive to be included in IEC 60601–1; and
- Particular standards, IEC 60601–2–XX, that tailor the general standard and collateral standards to specific devices by considering each requirement in them and determining if it should apply as stated, apply in modified form, or not apply at all.

The particular standards are ''customized'' versions of the general and collateral standards and can be used only with them.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document ''Use of IEC 60601 Standards; Medical Electrical Equipment'' is issued as a Level 1 guidance consistent with GGP's.

II. Overview

A party submitting a premarket application (i.e., premarket notification (510(k)), investigational device exemption application (IDE), premarket approval application (PMA), humanitarian device exemption application (HDE), or product development protocol (PDP)) must provide information as required by the statute and regulations to allow FDA to make an appropriate decision regarding the clearance or approval of the submission. This guidance document describes FDA's intent to use information on conformance with the IEC 60601 standards to satisfy premarket review requirements, but does not affect FDA's ability to obtain any information authorized by the statute or regulations.

FDA believes that conformance with the IEC 60601 standards provides a reasonable assurance of safety for many aspects of electromedical devices. Therefore, information on conformance with these standards will have a direct bearing on safety determinations made during the review of IDE's, HDE's, PMA's, and PDP's. In case of 510(k)s, information on conformance with the IEC 60601 standards will help establish the substantial equivalence of a new device to a legally marketed predicate device. This information can serve as a surrogate for comparative information to show that the new device is as safe as the predicate in the areas covered by the standards. Moreover, if a premarket submission contains a declaration of conformity to the IEC 60601 standards, this will, in most cases, eliminate the need to review actual test data for those aspects of the device addressed by the standards. The content of a declaration of conformity is described in the guidance document and is consistent with the ISO/IEC Guide 22.

Conformance with IEC 60601 standards in and of itself, however, may not always be a sufficient basis for regulatory decisions regarding safety. For example, a specific device may raise a safety issue not addressed by the standards, or a specific FDA regulation may require additional information beyond what conformity to the IEC 60601 standards provides. Under such circumstances, conformity with these standards will not satisfy all requirements regarding safety for marketing, or investigating, the product in the United States.

This guidance document represents the agency's current thinking on the use of IEC 60601 standards for medical electrical equipment. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information, including text, graphics, and files, that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the guidance document ''Use of IEC Standards; Medical Electrical Equipment,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The guidance document ''Use of IEC 60601 Standards Medical Electrical Equipment'' will be available at http://www.fda.gov/cdrh/ode/ecidraft.html.

A text-only version of the CDRH WWW site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to FDA's home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before April 13, 1998, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether to amend the current draft guidance.

Dated: November 25, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 98–751 Filed 1-12-98; 8:45 am]

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