Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mailstop E–03, Atlanta, GA 30333.

SUPPLEMENTARY INFORMATION: Consistent with OMB A–130 circular, Section 8.a.6.(j), Federal agencies are required to: ''Provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products * * *''.

The Division of Quarantine's Travelers' Health Voice/Fax service is a major part of the CDC Voice/Fax Information Service. This service allows any caller access to the most current health related information by using a Touch-Tone telephone. The service has been in operation for 7 years, and in the most recent 12-month period received nearly 1 million telephone calls, providing automated voice-response information to those callers; it also provided 1.5 million pages of automated fax information. Information is provided in several levels of detail and complexity to reach a broad audience more effectively, including the general public and health-care professionals.

The Travelers' Health Voice/Fax service is undergoing major renovation. With the innovations in telecommunications technology and the wide availability of fax machines, the voice component of this service is much less effective. The necessarily lengthy text is difficult to listen to and capture all critical recommendations. Analysis of call flow indicated ''caller hang-up'' before the complete message was delivered. Receipt of hard-copy fax documents ensures that travelers and their health-care providers have accurate and comprehensive messages. The fax system also permits their careful review of the complex information. Therefore, the voice component of the Travelers' Health Voice/Fax service will terminate in December 1997. The revised service will provide international travelers and health-care providers a more efficient and user-friendly service. The Travelers' Health Information will be available by fax through a toll-free call. In addition, the same information will be on the Internet on the CDC web site at: http://www.cdc.gov (select Travelers' Health).

Dated: January 7, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–746 Filed 1–12–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Consultation Services for Ship Construction and Renovation

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Extension of request for comments.

A notice requesting comments from all interested parties concerning an additional vessel size category for ships >90,000 gross register tonnage and charging fees for consultation services for ship construction and renovation was published in the **Federal Register** on November 17, 1997 (Volume 62, Number 221).

This notice is amended as follows: On page 61336, third column, under the heading **DATES,** the date for submitting written comments to this notice has been extended from January 2, 1998, to January 30, 1998.

All other information and requirements of the November 17, 1997, **Federal Register** notice remain the same.

Dated: January 7, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–747 Filed 1–12–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97P–0441]

Administrative Proceeding; Re: Pharmanex, Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of opportunity to comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing that comments related to the regulatory status of Cholestin™ may be submitted until January 30, 1998. This action is being taken as a part of the agency's deliberation on the regulatory status of Cholestin™. All comments postmarked on or before January 30, 1998, will be accepted as part of the official record for this matter.

DATES: Submit written comments by January 30, 1998.

ADDRESSES: Submit written comments regarding this issue to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, ATTN: Docket 97P–0441.

FOR FURTHER INFORMATION CONTACT: Ilisa B.G. Bernstein, Office of Policy (HF–23), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380, or IBernste@oc.fda.gov.

SUPPLEMENTARY INFORMATION: On October 29, 1997, FDA received a document entitled ''Petition to the Food and Drug Administration for a Stay of Action With Respect to Cholestin™ Dietary Supplement,'' (petition) from Pharmanex, Inc. (Pharmanex). The petition requested FDA to stay the effect of a September 30, 1997, FDA letter to Pharmanex discussing the regulatory status of Cholestin™, and to also stay any form of enforcement action adverse to Pharmanex or Cholestin™. In response to the petition, in a letter dated November 14, 1997, from William Schultz, FDA's Deputy Commissioner for Policy, to Stuart Pape, Counsel to Pharmanex, Inc., the agency informed the petitioner that it was not acting on the petition because there was no administrative action taken by the Commissioner of Food and Drugs capable of being stayed, and because FDA decisions to take enforcement actions are not subject to petitions or other action by interested persons outside the agency. In the November 14, 1997 letter, the agency also informed the petitioner that it was initiating an administrative proceeding under 21 CFR 10.25(b) to decide the regulatory status of Cholestin™. The agency stated that it would use its ''best efforts'' to conclude the proceeding by the end of 1997.

Since the November 14, 1997, letter was issued, FDA has received a number of comments regarding the regulatory status of Cholestin™, including three additional submissions from Pharmanex (one received by the agency on December 29, 1997). Several requests for extensions of time to submit comments have also been received. Under the circumstances, it is apparent that additional time is required to afford all interested parties adequate opportunity to submit comments in this matter.

With this notice the agency announces that comments related to this matter may be submitted until January 30, 1998. All comments postmarked on or before January 30, 1998, will be accepted as part of the official record for this matter. Comments should be sent to the Dockets Management Branch (address above) and should be identified

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