

**1996 Federal Register (Vol 61) January - December****October****Vol. 61 No. 211 Wednesday, October 30, 1996****Food and Drug Administration****Meetings: Advisory committees, panels, etc., << 55990>>**

★ First Match

**Food and Drug Administration****NOTICES****Meetings: Advisory committees, panels, etc., << 55990>>**

Vol. 61 No. 211 Wednesday, October 30, 1996 p &lt;&lt; 55990&gt;&gt; (Notice) 1/201

-----  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

†  
-----

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:  
Joint: Meeting of the Nonprescription Drugs Advisory Committee, the Advisory Committee for Reproductive Health Drugs, the Anti-Infective Drugs Advisory Committee, and the Antiviral Drugs Advisory Committee  
Date, time, and place. November 20, 1996, 1 p.m., and November 21 and 22, 1996, 8:30 a.m., Holiday Inn--Gaithersburg, Ballroom, Two

Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, November 20, 1996, 1 p.m. to 3 p.m.; open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 5:30 p.m.; open committee discussion, November 21, 1996, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; open public hearing, November 22, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kennerly K. Chapman, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or e-mail chapmank@cderr.fda.gov, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541. Please call the hotline for information concerning any possible changes.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Advisory Committee for Reproductive Health Drugs reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties. The 'Anti-Infective Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders. The Antiviral Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda--Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 6, 1996, 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 required to make their comments.

Open committees discussion. On November 20, 1996, the committees will jointly discuss issues relevant to the use of microbicidal topical vaginal agents against infection with sexually transmitted Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC). In light of the significant public health impact of these sexually transmitted diseases, and the difficulties related to the evaluation and promotion of topical vaginal agents as prophylaxis against CT and GC, FDA is soliciting opinions and advice from the advisory committees regarding the development of policy for topical vaginal bacteriocidal agents. Issues for discussion include: (1) The quality and type of data that are available to support the use of such agents as prophylaxis against CT and GC, (2) what additional data would be required by the agency to create a label for such agents, and (3) whom would the appropriate target audience be for such agents. The agency encourages investigators, academicians, and members of the pharmaceutical industry with information about the use of such agents as prophylaxis against infection with CT and GC to respond to this notice. On November 21, 1996, the committees will discuss guidelines for the development of vaginal products for preventing the transmission of the human immunodeficiency virus (HIV). On November 22, 1996, the committees will

discuss proposals and guidances for clinical efficacy studies on marketed OTC vaginal spermicides. Issues for discussion will include the type of data and quality of both in vitro and in vivo data needed to support and ensure spermicidal efficacy in final formulation.

Antiviral Drugs Advisory Committee

Date, time, and place. November 22, 1996, 8:30 a.m., Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

---- page 55991 ----

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4:30 p.m.; Rhonda W. Stover, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda--Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 15, 1996, 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 required to make their comments.

Open committee discussion. The committee will discuss data relevant to new drug application (NDA) 20-705, Rescriptor(R), (delavirdine, Pharmacia and Upjohn Co.) for use in the treatment of HIV infection.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 22, 1996.

Michael A. Friedman,  
Deputy Commissioner for Operations.  
[FR Doc. 96-27854 Filed 10-29-96; 8:45 am]  
BILLING CODE 4160-01-F

.....  
The Contents entry for this article reads as follows:

Meetings:

Advisory committees, panels, etc., << 55990>>