

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 functions 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 September 20, 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. On September 26, 1996, the committee will discuss data relevant to the approved drug, saquinavir (Invirase™, Hoffmann-La Roche), for use in combination with nucleoside analogues for the treatment of human immunodeficiency virus (HIV) infection. On September 27, 1996, the committee will discuss data relevant to new drug application 20-705, delavirdine (Rescriptor®, 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 each meeting 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, 5600 Fishers Lane, rm. 12A-16, 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, 12420 Parklawn Dr., rm. 1-23, 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: August 27, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96-22485 Filed 9-3-96; 8:45 am]
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Bioresearch; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Nashville District Office, and the Center for Drug Evaluation and Research) is announcing a free public workshop on FDA regulatory requirements for the bioresearch industry. The workshop is designed to assist the industry in complying with regulations for clinical investigators, institutional review boards, and sponsor-monitors.

DATES: The public workshop will be held on Tuesday, September 24, 1996, from 8:45 a.m. to 4:45 p.m.

ADDRESSES: The public workshop will be held at the University of Alabama—Birmingham, University Hospital, 620 South 19th St., Spain Wallace Bldg., Margaret Cameron Spain Auditorium, rm. S100, Birmingham, AL.

FOR FURTHER INFORMATION CONTACT: William H. Oates, FDA's Nashville District Office, 296 Plus Park Blvd., Nashville, TN 37217, 615-781-5374 ext. 118, FAX 615-781-5391.

Those persons interested in attending this meeting should FAX their registration, including name(s), firm name, address, telephone and FAX numbers, and any specific questions to William H. Oates (address above) by September 13, 1996. There is no registration fee for this workshop. Space is limited, therefore, interested parties are encouraged to register early.

SUPPLEMENTARY INFORMATION: FDA's survey of the bioresearch industry shows that many of these firms are either unaware of applicable regulations and guidelines or not in compliance with applicable requirements. This workshop is designed to assist the bioresearch industry in complying with applicable regulations.

Dated: August 23, 1996.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
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