

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 (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 16, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95-26053 Filed 10-19-95; 8:45 am]

BILLING CODE 4160-01-F

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:

Antiviral Drugs Advisory Committee

Date, time, and place. November 6 and 7, 1995, 8:30 a.m., and November 8, 1995, 8 a.m., Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, November 6, 1995, 8:30 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; open committee discussion, November 7, 1995, 8:30 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; open committee discussion, November 8, 1995, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and

Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531.

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 a contact person before October 31, 1995, 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 November 6, 1995, the committee will discuss data relevant to new drug applications (NDA's) 20-564 (tablets) and 20-596 (oral solution) for lamivudine (Epivir™, also known as 3TC), sponsored by Glaxo Wellcome. On November 7, 1995, the committee will discuss data relevant to NDA 20-628 for saquinavir (Invirase™), sponsored by Hoffman-La Roche. On November 8, 1995, the committee will discuss confirmatory trials of stavudine (Zerit™, also known as d4T), sponsored by Bristol-Myers Squibb. All products listed above are for the treatment of human immunodeficiency virus infection.

Closed committee deliberations. On November 8, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Biological Response Modifiers Advisory Committee

Date, time, and place. November 13, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person.

Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last

that long; open committee discussion, 9 a.m. to 1 p.m.; open public hearing, 1 p.m. to 1:15 p.m., unless public participation does not last that long; open committee discussion, 1:15 p.m. to 4:15 p.m.; closed committee deliberations, 4:15 p.m. to 6 p.m.; William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Biological Response Modifiers Advisory Committee, code 12388.

General function of the committee.

The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

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 5, 1995, 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: (1) Product license application supplement, reference number 95-0100, for GM-CSF Immunex Corp., for peripheral stem cell mobilization; and (2) product license application supplement, reference number 95-0475, for G-CSF, Amgen Inc., also for the same indication (peripheral stem cell mobilization).

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. November 17, 1995, 8 a.m., Parklawn Bldg., conference rooms G, H, I, and J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9

a.m. to 4 p.m.; closed committee deliberations, 4 p.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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 9, 1995, 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 be briefed on the Pediatric Labeling Rule and the data necessary to support pediatric labeling of drugs. The committee will discuss NDA 20-114, Astelin nasal spray (azelastine), for seasonal allergic rhinitis. The sponsor is Carter-Wallace, Inc.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b (c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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.

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The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so

designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and

information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (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 17, 1995.
David A. Kessler,
Commissioner of Food and Drugs.
[FR Doc. 95-26151 Filed 10-19-95; 8:45 am]
BILLING CODE 4160-01-F

Health Resources and Services Administration

Notice of filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Service Administration's Federal Advisory Committee has been filed with the Library of Congress:

Advisory Committee on Infant Mortality

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue SE., Washington, DC. Copies may be obtained from: Ms. Kerry P. Nessler, Maternal & Child Health Bureau, Health Resources and Services Administration, Room 18-20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2204.

Date: October 17, 1995.
Jackie E. Baum,
Advisory Committee Management Officer,
HRSA.
[FR Doc. 95-26052 Filed 10-19-95; 8:45 am]
BILLING CODE 4160-15-P

Proposed Data Collections Available for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects:

1. Organ Procurement and Transplantation Network Regulations—42 CFR Part 121 (Final Rule)

(OMB No. 0915-0184)—Extension and Revision—This final rule establishes the policies governing the Organ Procurement and Transplantation Network (OPTN). These rules will regulate the operation of the OPTN in four major areas: membership requirements, patient listing, organ allocation, and record maintenance and recording. The final rule contains three requirements not currently approved under the Paperwork Reduction Act, as indicated in the table below (footnote 2). The burden estimates are as follows:

Title	Number of respondents	Frequency of response	Hours per response	Total burden hours
121.3(a)(6)(ii) (Reporting) Submission of Policies & Procedures	1	4	0.5	2
121.3(a)(6)(ii) ² (Disclosure) Sending policies & procedures to OPOs	1	16	75	1,200
121.3(d)(1) (Reporting) Application requirements for OPOs, hospitals, & others	2,774	³ 1	0.5	1,387
121.5(c) ² (Reporting) Submitting criteria for organ accept.	115	1	0.1	12
121.5(c) ² (Disclosure) Sending criteria to OPOs	115	1	0.1	12
121.6(b)(4) (Reporting) Reasons for refusal	828	14	0.1	1,200
121.7(e) (Reporting) Transplant to prevent organ wastage	278	4	0.1	111
121.8(b) (Reporting) Application requirements for transplant centers:				
A. Medicare/Medicaid Approved programs & VA Hospitals	308	³ 1	0.5	154
B. Other programs	350	³ 1	2.0	700