

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.

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: June 15, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95-15147 Filed 6-20-95; 8:45 am]

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National Institutes of Health

Notice of Meeting of the NIH Director's Advisory Panel on Clinical Research

Notice is hereby given that the NIH Director's Advisory Panel on Clinical Research, a group reporting to the Advisory Committee to the Director (ACD), National Institutes of Health (NIH), will meet in public session at the William H. Natcher Building (Building 45) Conference Center, Conference Room E1/E2, National Institutes of Health, Bethesda, Maryland 20892, on July 7, 1995, from 8:30 a.m. until approximately 3:30 p.m.

The goal of the Panel is to review the status of clinical research in the United States and to make recommendations to the ACD about how to ensure its effective continuance. Topics to be considered at this and subsequent meetings will include, but not be limited to, financing of clinical research; roles of the General Clinical Research Centers and the NIH Clinical Center; attracting and training future clinical researchers; conduct of clinical trials; and peer review of clinical research.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other special accommodations, should contact the person named below in advance of the meeting.

Attendance may be limited to seat availability. If you plan to attend the meeting as an observer or if you would like additional information, please contact Mrs. Janet Smith, National Institutes of Health, Building 10, Room 1C-116, 10 Center Drive, MSC 1154, Bethesda, Maryland 20892-1154, telephone (301) 402-3444, fax (301) 402-3443, by June 30, 1995.

Effective Date: June 15, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

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National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Gene Nutrient Interaction in the Pathogenesis of Congenital Heart Defects.
Date: July 10-11, 1995.

Time: 7 p.m.

Place: Holiday Inn, Bethesda, Maryland.

Contact Person: Anthony M. Coelho, Jr., M.D., Two Rockledge Building, 6701 Rockledge Drive, Room 7182, Bethesda, Maryland 20892-7924, (301) 435-0277.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: SCOR on Ischemic Heart Disease in Blacks.

Date: July 19-20, 1995.

Time: 7 p.m.

Place: Holiday Inn, Chevy Chase, Maryland.

Contact Person: S. Charles Selden, Ph.D., Two Rockledge Building, 6701 Rockledge Drive, Room 7196, Bethesda, Maryland 20892-7924, (301) 435-0288.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in