

subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 9, 1996.

George H. Pauli,  
Acting Director, Office of Premarket  
Approval, Center for Food Safety and Applied  
Nutrition.

[FR Doc. 96-20438 Filed 8-9-96; 8:45 am]

BILLING CODE 4160-01-F

### Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

**MEETING:** The following advisory committee meeting is announced:

#### Food Advisory Committee

*Date, time, and place.* August 27 and 28, 1996, 8:15 a.m., Marriott Hotel-Metro Center, Grand Ballroom Salons A, B, and C, 775 12th St. NW., Washington, DC.

*Type of meeting and contact person.* Open committee discussion, August 27, 1996, 8:15 a.m. to 3 p.m.; open public hearing, 3 p.m. to 5 p.m., unless participation does not last that long; open committee discussion, August 28, 1996, 8:15 a.m. to 4 p.m.; Lynn A. Larsen, Center for Food Safety and

Applied Nutrition (HFS-5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4727, or Catherine M. DeRoeve (address above), Advisory Committee Staff (HFS-22), 202-205-4251, FAX 202-205-4970, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Food Advisory Committee, code 10564. Please call the hotline for information concerning any possible changes.

#### *General function of the committee.*

The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

#### *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 by close of business August 21, 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. If necessary, comments may be limited to 5 minutes.

*Open committee discussion.* The Food Advisory Committee and the Ephedra Working Group will discuss the actions and recommendations made by the working group during its October 11 and 12, 1995, meeting. Additional information that has become available to FDA since that time will also be presented during the meeting. The committee will be asked to consider the original working group's recommendations in light of this new information.

Under 21 CFR 14.20 and 14.35, interested persons may submit written information or views on the matter(s) before the committee. Voluminous data are to be accompanied by a summary. Submissions must be made to the Executive Secretary and not directly to any committee members. Substantive submissions received at least 3 weeks prior to a meeting may be included in members' briefing materials; submissions received later will be distributed at the committee meeting. All submissions that include copyrighted materials must be accompanied by documented permission for duplication and distribution at no copyright expense to FDA.

At least 50 copies of each submission must be provided; sufficient additional copies may be requested by the agency

for distribution to the public at a meeting. Fewer copies of voluminous submissions will be required; only summaries of such submissions will be provided to committee members, with complete copies of submissions being made available for circulation among committee members and for viewing by the public at a meeting.

More detailed information regarding the meeting agenda that may become available prior to the meeting will be provided to the public via the 800 number given above.

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 (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 6, 1996.

David A. Kessler,

*Commissioner of Food and Drugs.*

[FR Doc. 96-20523 Filed 8-9-96; 8:45 am]

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## National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

*Name of SEP:* Biostatistical Grant Application in Response to RFA 96-001, Pediatric AIDS Clinical Trials Group.  
*Date:* September 9-11, 1996.  
*Time:* 7:00 p.m.  
*Place:* Hyatt Regency, Two Fountain Plaza, Buffalo, NY 14202, (716) 856-1234.  
*Contact Person:* Dr. Madelon C. Halula, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C16, Bethesda, MD 20892, (301) 402-2636.  
*Purpose/Agenda:* To evaluate scientific and technical merit of a grant application.

The meeting will be closed in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: August 6, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-20392 Filed 8-9-96; 8:45 am]

BILLING CODE 4140-01-M

### Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

*Purpose/Agenda:* To review individual grant applications.

*Name of SEP:* Microbiological and Immunological and Sciences.

*Date:* August 13, 1996.

*Time:* 1:30 p.m.

*Place:* NIH, Rockledge 2, Room 4182, Telephone Conference.

*Contact Person:* Dr. William Branche, Jr., Scientific Review Administrator 6701 Rockledge Drive, Room 4182, Bethesda, Maryland 20892, (301) 435-1148.

*Name of SEP:* Biological and Physiological Sciences.

*Date:* August 16, 1996.

*Time:* 1:00 p.m.

*Place:* NIH, Rockledge 2, Room 4142, Telephone Conference.

*Contact Person:* Dr. Edmund Copeland, Scientific Review Administrator, 6701 Rockledge Drive, Room 4142, Bethesda, Maryland 20892, (301) 435-1715.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

*Name of SEP:* Clinical Sciences.

*Date:* November 4-6, 1996.

*Time:* 8:00 a.m.

*Place:* DoubleTree Hotel, Rockville, MD.  
*Contact Person:* Dr. Gertrude McFarland, Scientific Review Administrator, 6701 Rockledge Drive, Room 4110, Bethesda, Maryland 20892, (301) 435-1284.

*Name of SEP:* Clinical Sciences.

*Date:* December 9, 1996.

*Time:* 8:00 a.m.

*Place:* DoubleTree Hotel, Rockville MD.  
*Contact Person:* Dr. Gertrude McFarland, Scientific Review Administrator, 6701

Rockledge Drive, Room 4110, Bethesda, Maryland 20892, (301) 435-1284.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Date: August 6, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-20393 Filed 8-9-96; 8:45 am]

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### Office of Research on Women's Health; Notice of Meeting—"Beyond Hunt Valley: Research on Women's Health for the 21st Century"

Notice is hereby given that the Office of Research on Women's Health, Office of the Director, National Institutes of Health, will convene a meeting on September 25, 26, and 27, 1996, at the DoubleTree Hotel Philadelphia, Broad Street at Locust, Philadelphia, Pennsylvania.

The purpose of the meeting is to update the current biomedical and behavioral research agenda for women's health, as presented in the Report of the National Institutes of Health:

Opportunities for Research on Women's Health, a publication based on a conference held in Hunt Valley, Maryland, September, 1991.

The first day, September 25, from 1:00 to 6:00 p.m., will be devoted to receiving public testimony from individuals representing organizations interested in biomedical and behavioral research on women's health issues. On September 26 and 27, concurrent working groups will discuss areas of science particularly relevant to women's health with attention to research design, health impact of collaborative and multidisciplinary research efforts, and issues of importance to young investigators. The meeting of September 26 will be from 9:00 a.m. to 5:30 p.m., and that of September 27 from 9:30 a.m. to approximately 3:30 p.m. All sessions of the meeting are open to the public.

Experts in fields of basic and clinical science; practitioners interested in women's health; representatives of scientific, professional and women's health organizations; and women's