

sponsors are the: European Commission; European Federation of Pharmaceutical Industries Associations; Japanese Ministry of Health, Labour, and Welfare; Japanese Pharmaceutical Manufacturers Association, Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the style before publication.

In September 2002, the ICH Steering Committee agreed that a draft guidance entitled "Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs" should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH focusing on pharmacovigilance topics. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The ICH E2C guidance of May 19, 1997, recommends a unified standard for the format, content, and reporting frequency for PSURs for drug and biological products. This draft guidance, an addendum to the ICH E2C guidance, provides additional information on the objectives, general principles, and model for PSURs. The draft guidance includes, for example, recommendations regarding:

- Synchronization of National Birthdates with the International Birthdates,

- Use of the latest version of the reference safety information,
- Submission of executive summaries as part of the PSUR,
- Options to submit summary bridging reports and addendum reports, and
- Handling of solicited reports.

The document should be used in conjunction with the E2C guidance.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by January 24, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: December 23, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02-32979 Filed 12-30-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of 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 a meeting of the National Advisory Research Resources Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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

Name of Committee: National Advisory Research Resources Council.

Date: January 23, 2003.

Open: 8:30 a.m. to 2:45 p.m.

Agenda: Report of Center Director and other issues.

Place: National Institutes of Health, Building 31C, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: 2:45 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31C, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PhD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892. 301-496-6023.

Information is also available on the Institute's/Center's home page: <http://www.ncrr.nih.gov/newspub/minutes.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: December 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-33022 Filed 12-30-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of 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 a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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

Name of Committee: National Advisory Eye Council.

Date: January 23–24, 2003.

Closed: January 23, 2003, 8:30 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Room G, Rockville, MD 20852.

Open: January 23, 2003, 1:15 p.m. to 5 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by staff of the Institute and discussions concerning Institute programs and policies.

Place: 6130 Executive Boulevard, Room G, Rockville, MD 20852.

Open: January 24, 2003, 8:30 a.m. to 12 p.m.

Agenda: Program Planning.

Place: 6130 Executive Boulevard, Room G, Rockville, MD 20852.

Contact Person: Lore Anne McNicol, Director, division of Extramural Research, National Eye Institute, National Institutes of Health, Bethesda, MD 20892, (301) 496–9110.

Information is also available on the Institute's/Center's home page: <http://www.nei.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 20, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–33027 Filed 12–30–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 meeting.

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

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Genetics of Reverse Cholesterol Transport.

Date: January 10, 2003.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contract Person: Valerie L. Prenger, PhD, Health Scientist Administrator, Review Branch, Room 7194, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892–7924, (301) 435–0288.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838; Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 19, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–33025 Filed 12–30–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 meeting.

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

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Novel HIV Therapies: Integrated Preclinical/Clinical Program (IPCP).

Date: January 16–17, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Anthony Macaluso, PhD, Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700–B Rockledge Drive, MSC 7616, Room 2153, Bethesda, MD 20892, 301–402–0643, amacaluso@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–33023 Filed 12–30–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 meeting.

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