

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1994. FDA has announced the availability of previous lists, which are brought up to date monthly, identifying the drugs and biologics granted orphan-drug designation pursuant to the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and the Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4718.

FOR FURTHER INFORMATION CONTACT: Peter L. Vaccari, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4718.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and acts on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologics. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologics, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses. The cumulative list of compounds receiving orphan-drug designation through 1988 was published in the **Federal Register** of April 21, 1989 (54 FR 16294). This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify Docket No. 84N-0102, which is the docket number for this notice.

The list that is the subject of this notice consists of designated orphan drugs and biologics through December 31, 1994, and, therefore, brings the May 9, 1994 (59 FR 23888) publication up to date.

The orphan-drug designation of a drug or biologic applies only to the sponsor who requested the designation. Each sponsor interested in developing

an orphan drug or biologic must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for those products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: April 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-9700 Filed 4-18-95; 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 Committees have been filed with the Library of Congress:

Departments of Family Medicine Review Committee

Faculty Development Review Committee

Graduate Training in Family Medicine

Review Committee

Predoctoral Training Review Committee

Residency Training Review Committee

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, D.C. Copies may be obtained from: Ms. Sherry Whipple, Executive Secretary, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6874.

Dated: April 14, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 95-9699 Filed 4-18-95; 8:45 am]

BILLING CODE 4160-15-P

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of meetings of the National Institute of Neurological Disorders and Stroke (NINDS).

The National Advisory Neurological Disorders and Stroke Council and its subcommittee meetings will be open to the public as indicated below. Attendance by the public will be limited to space available.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary or the Scientific Review Administrator indicated. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary listed for the meeting.

Name of Committee: The Planning Subcommittee of the National Advisory Neurological Disorders and Stroke Council.

Date: May 31, 1995.

Place: National Institutes of Health, Building 31, Conference Room 8A28, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 1:30 p.m.-3 p.m.

Agenda: To discuss program planning and fiscal matters.

Closed: 3 p.m.-recess.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Dates: June 1-2, 1995.

Place: National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

Open: June 1, 9 a.m.-2 p.m.

Agenda: A report by the Director, NINDS; a report by the Director, Division of Extramural Activities, NINDS; and a presentation by an NINDS grantee.

Closed: June 1, 2 p.m.-recess; June 2, 8:30 a.m.-adjournment.

Executive Secretary: Constance W. Atwell, Ph.D., Director, Division of Extramural Activities, NINDS, National Institutes of

Health, Bethesda, MD 20892, Telephone: (301) 496-9248.

The following meetings will be totally closed to review and evaluate grant applications.

Name of Committee: Neurological Disorders Program Project Review A Committee.

Date: June 5-7, 1995.

Time: June 5, 7:30 p.m.-recess; June 6, 8:30 a.m.-recess; June 7, 8:30 a.m.-adjournment.

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

Contact Person: Dr. Katherine Woodbury, Scientific Review Administrator, National Institutes of Health, Federal Building, Room 9C14, Bethesda, MD 20892, (301) 496-9223.

Name of Committee: Training Grant and Career Development Review Committee.

Date: June 15-16, 1995.

Time: June 15, 7:30 p.m.-recess; June 16, 8 a.m.-adjournment.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20892.

Contact Person: Dr. Alfred Gordon, Scientific Review Administrator, National Institutes of Health, Federal Building, Room 9C14, Bethesda, MD 20892, (301) 496-9223.

Name of Committee: Neurological Disorders Program Project Review B Committee.

Date: June 26-28, 1995.

Time: June 26, 8 a.m.-recess; June 27, 8 a.m.-recess; June 28, 8 a.m.-adjournment.

Place: Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dr. Paul Sheehy, Scientific Review Administrator, National Institutes of Health, Federal Building, Room 9C10, Bethesda, MD 20892, (301) 496-9223.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research Related to Neurological Disorders; No. 93.854, Biological Basis Research in the Neurosciences).

Dated: April 11, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-9607 Filed 4-18-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute on Deafness and Other Communication Disorders; Notice of a Meeting of the Epidemiology and Biometry Research Program Working Group of the National Deafness and Other Communication Disorders (NDCD) Advisory Council

Notice is hereby given of the meeting of the Epidemiology and Biometry Research Program Working Group of the NDCD Advisory Council on April 27, 1995. The meeting will take place from 11 a.m. to 4 p.m. in Conference Room 3C05, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

The meeting, which is open to the public, will be held to discuss concept

clearance of several scientific projects in the hearing and other communication disorders areas. Attendance by the public is limited to the space available.

Summaries of the meeting and a roster of members may be obtained from Ms. Debbie D'Angelo, Program Analyst, National Institute on Deafness and Other Communication Disorders, Executive Plaza South, Room 430, 6120 Executive Blvd., Bethesda, Maryland 20892, 301-402-1843, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. D'Angelo in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: April 12, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-9608 Filed 4-18-95; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Notice of Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the National Cancer Institute for May and June 1995.

These meetings will be open to the public to discuss administrative details or other issues relating to committee activities as indicated in the notice and for the review of concepts being considered for funding. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review and discussion of previous site visit reports and evaluation of current contracts and for the critique and evaluation of extramural/intramural programmatic and personnel policies, including consideration of personnel qualifications and performance and the competence of individual investigators. These contracts and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the programs, projects, and contracts, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Carole Frank, the Committee Management Officer, National Cancer Institute, Executive Plaza North, Room

630E, 6130 Executive Blvd MSC 7405, Bethesda, Maryland 20892-7405, (301-496-5708) will provide a summary of the meetings and the roster of committee members, upon request. Other information pertaining to the meetings may be obtained from the contact person indicated below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed for that particular meeting.

Committee Name: Board of Scientific Counselors, Division of Cancer Prevention and Control.

Contact Person: Ms. Linda M. Bremerman, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Rm 232, 6130 Executive Blvd., Rockville, MD 20892-7094, Telephone: (301) 496-8526.

Date of Meeting: May 4-5, 1995.

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

Open: May 4, 1995 10:45 am to 5 pm May 5, 1995 8:30 am to 11:30 am.

Agenda: Review progress of programs within the Division and review of concepts being considered for funding.

Closed: May 5, 1995 11:30 am to adjournment.

Agenda: Extramural/Intramural programmatic and personnel policies of a sensitive nature and consideration of personnel qualifications and performance and the competence of individual investigators.

Committee Name: Cancer Control Science and Surveillance Subcommittee of the Board of Scientific Counselors, Division of Cancer Prevention and Control.

Contact Person: Ms. Linda M. Bremerman, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Rm 232, 6130 Executive Blvd., Rockville, MD 20892-7994, Telephone: (301) 496-8526.

Date of Meeting: May 4, 1995.

Place of Meeting: Building 31, Conference Room 8, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 8:30 a.m. to 10:30 a.m.

Agenda: Discuss current and future programs of the subcommittee and review of concepts being considered for funding.

Committee Name: Cancer Prevention Research Subcommittee of the Board of Scientific Counselors, Division of Cancer Prevention and Control.

Contact Person: Ms. Linda M. Bremerman, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Rm 232, 5130 Executive Blvd., Rockville, MD 20892-7094, Telephone: (301) 496-8526.

Date of Meeting: May 4, 1995.

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

Open: 8:30 a.m. to 10:30 a.m.

Agenda: Discuss current and future programs of the subcommittee and review of concepts being considered for funding.