

**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.*

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## 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.*

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## 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