Because of these serious deviations, FDA concluded that the management at PCBB did not adequately demonstrate the ability to operate the establishment in a manner that assured compliance with Federal regulations or accepted standard operating procedures, or to ensure that personnel were adequately trained and supervised and had a thorough understanding of the procedures that they performed as required by 21 CFR 600.10(a) and (b) and 606.20(a) and (b). These conditions at PCBB were considered to constitute a danger to public health warranting license suspension pursuant to 21 CFR 601.5(b) and 601.6(a). FDA accordingly suspended the firm's licenses by letter dated November 6, 1992.

In addition to the suspension of establishment and product licenses, and in order to preclude the distribution of violative units, and to address those questionable units already in distribution channels, FDA requested that PCBB immediately and concurrently perform the following: (1) Review test records for antibody to the human immunodeficiency virus (Type I), and then identify and defer all donors who may have been misinterpreted as suitable due to improper donor reentry procedures; (2) develop and implement a plan to identify and defer all donors who, during the medical history interview, have provided information which may deem such donors as ineligible, and (3) identify and recall all units collected from such donors, and notify all consignees of transfusible and nontransfusible blood and blood components of the test/medical history of the units. In a letter to the firm dated March 9, 1994, FDA concluded that the recall was complete.

In a letter to FDA dated April 29, 1994, PCBB voluntarily requested that its licenses be revoked and thereby waived its opportunity for a hearing. The agency granted the request in a letter dated June 3, 1994, which revoked the establishment and product licenses.

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 1121) and the product licenses for the manufacture of Whole Blood, Red Blood Cells, Platelets, and Plasma issued to Putnam County Blood Bank, Inc., Palatka, FL, were revoked, effective June 3, 1994.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: April 11, 1995.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 95–9577 Filed 4–18–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0090]

Dietary Supplements: Notice of Withdrawal of Regulatory Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has withdrawn a number of import alerts, import bulletins, and compliance policy guides involving dietary supplements. FDA has taken these actions to conform its regulatory guidance to the changes made to the Federal Food, Drug, and Cosmetic Act (the act) by the Dietary Supplement Health and Education Act (DSHEA).

FOR FURTHER INFORMATION CONTACT: Loretta A. Branch Carey, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–205–5372.

SUPPLEMENTARY INFORMATION: On October 25, 1994, the President signed into law the DSHEA (Pub. L. 103–417). Among the most significant changes in the act made by the DSHEA is the addition of section 201(s)(6) (21 U.S.C. 321(s)(6)), which excepts dietary ingredients of dietary supplements from coverage under the food additive provisions of the act (section 3(b) of the DSHEA). As a result of this change, such ingredients are no longer subject to a premarket safety review.

In response to this change, FDA has reviewed the regulatory guidance that it issues to its field offices to conform that guidance to the change. As a result of this review, FDA has found that it is appropriate to withdraw the following import alerts, import bulletins, and compliance policy guides because they are no longer consistent with the act.

A. Compliance Policy Guides

1. CPG 7117.04, entitled ''Botanical Products for use as Food''
2. CPG 7118.01, entitled ''Dietary Supplements-Misbranding Nutritionally Insignificant Ingredients''

B. Import Alerts

1. 24–14 Products containing Bracken
2. 26–02 Flaxseed/Linseed Oil
3. 54–03 Carnitine
4. 54–05 Ultra Bios 2000 Food Supplement
5. 66–02 Ginseng
6. 66–04 Oil of Evening Primrose

C. Import Bulletins

1. 31–B01 Selfheal Flower, Prunella Vulgaris
2. 54–B06 Tricosanthis
3. 66–B62 Ephedra

The Agency continues to review and revise the remaining related import alerts, bulletins, and compliance policy guides, in order to comply with DSHEA.

FDA notes that it does not usually give notice in the **Federal Register** of its issuance or withdrawal of import alerts or bulletins. It is doing so in this instance, however, because of the on-going congressional interest in FDA's implementation of the DSHEA. FDA advises that issuing this notice does not mark any type of change in the agency's usual procedures for issuing or withdrawing these alerts or bulletins.

In response to the DSHEA, FDA has also reassessed its general enforcement priorities with respect to dietary supplements. FDA advises that in enforcing the act with respect to these products, its primary focus is likely to be, as it always has been, on safety concerns. The agency advises, however, that its regulatory priorities are subject to adjustment in response to changing circumstances. For example, the labeling of dietary supplements will likely be given a higher priority by the agency after December 31, 1996, when compliance with FDA's nutrition labeling and nutrient content claim regulations for dietary supplements is to begin.

Dated: April 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9702 Filed 4–18–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 84N–0102]

Cumulative List of Orphan-Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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