Dated: May 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12011 Filed 5–26–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 the cumulative list of orphan drug and biological designations as of December 31, 2003. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fritsch, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological 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 cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 2003, and, therefore, brings the April 15, 2003 (68 FR 18247) publication up to date. This list is available upon request from the Division of Dockets Management (see **ADDRESSES**). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this document. In addition, the list is updated monthly and is available upon request from OPD or FDA's Division of Dockets Management (see **ADDRESSES**). The current list is also available on the Web site, *http://www.fda.gov/orphan*.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan 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 (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (see **ADDRESSES**).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: May 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11948 Filed 5–26–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2005.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this document.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons:

1. *For the device panels*: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022, e-mail: *NJP@CDRH.FDA.GOV*.

2. *For the National Mammography Quality Assurance Advisory Committee, excluding consumer representatives*: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *CAF@CDRH.FDA.GOV*.

3. *For health professionals, industry representatives and government representatives for the Device Good Manufacturing Practice Advisory Committee*: Sharon Kalokerinos, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, e-mail: *SMK@CDRH.FDA.GOV*.

4. *For government representatives and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee*: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, *RVK@CDRH.FDA.GOV*.