

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.

FOR FURTHER INFORMATION CONTACT:

Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION:**I. Vacancies**

FDA is requesting nominations of voting members for vacancies listed as follows:

1. Anesthesiology and Respiratory Therapy Devices Panel: Two vacancies occurring November 30, 2004; anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilatory support, pharmacology, physiology, or the effects and complications of anesthesia.

2. Circulatory System Devices Panel: Three vacancies occurring June 30, 2004; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

3. Ear, Nose, and Throat Devices Panel: Three vacancies occurring October 31, 2004; otologists, neurotologists, audiologists, hearing scientists and electrophysiologists.

4. Gastroenterology and Urology Devices Panel: Three vacancies occurring December 31, 2004; urologists and nephrologists.

5. General and Plastic Surgery Devices Panel: One vacancy occurring August 31, 2004, two vacancies occurring August 31, 2005; general surgeons, plastic surgeons, thoracic surgeons, abdominal surgeons, pelvic surgeons and reconstructive surgeons, biomaterials experts, laser experts, wound healing experts or endoscopic surgery experts.

6. General Hospital and Personal Use Devices Panel: Three vacancies occurring December 31, 2004; internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

7. Hematology and Pathology Devices Panel: Three vacancies immediately, one vacancy occurring February 28, 2005; hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular biologists with special interests in

development of predictive and prognostic biomarkers.

8. Immunology Devices Panel: Two vacancies occurring February 28, 2005; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

9. Microbiology Devices Panel: Three vacancies occurring February 28, 2005; infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists.

10. Neurological Devices Panel: Two vacancies occurring November 30, 2004; neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pain management and movement disorders), interventional neuroradiologists, psychiatrist, biostatisticians.

11. Obstetrics and Gynecology Devices Panel: Two vacancies occurring January 31, 2005; experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.

12. Ophthalmic Devices Panel: Three vacancies occurring October 31, 2004; ophthalmologists specializing in cataract and refractive surgery and surgical retina, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.

13. Orthopaedic and Rehabilitation Devices Panel: Two vacancies occurring August 31, 2005; doctors of medicine or philosophy with experience in tissue engineering, biomaterials or tribology; orthopedic surgeons experienced with prosthetic ligament devices, joint implants, or spinal devices; physical therapists experienced in spinal cord injuries, neurophysiology, electrotherapy, and joint biomechanics; rheumatologists; biomedical or biomechanical engineers.

14. Radiological Devices Panel: Two vacancies occurring January 31, 2005; a medical physicist with experience in the calibration, design and use of diagnostic and therapeutic devices, and an interventional radiologist with experience in the imaging, evaluation and treatment of patients with various types of diseases and malignancies.

15. National Mammography Quality Assurance Advisory Committee: Five vacancies occurring January 31, 2005; one interpreting physician, one radiological technologist, one medical physicist, and two other health professionals whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.

16. Device Good Manufacturing Practice Advisory Committee: Six vacancies immediately; three government representatives, two industry representatives, and one health professional; one vacancy occurring May 31, 2005; one health professional.

17. Technical Electronic Product Radiation Safety Standards Committee: Three vacancies immediately, two government representatives and one industry representative.

II. Functions**A. Medical Devices Advisory Committee**

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area performs the following duties: (1) Advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; (2) advises on any possible risks to health associated with the use of devices; (3) advises on formulation of product development protocols; (4) reviews premarket approval applications for medical devices; (5) reviews guidelines and guidance documents; (6) recommends exemption of certain devices from the application of portions of the act; (7) advises on the necessity to ban a device; and (8) responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each

panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or agency decisions or actions.

B. National Mammography Quality Assurance Advisory Committee

The functions of the committee are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

C. Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations for issuance regarding good manufacturing

practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the act (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) two shall be representatives of the interests of the general public.

D. Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the act (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990, provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental agencies, including State or Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor.

III. Qualifications

A. Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels shall have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related

professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a government representative or health professional should have knowledge of or expertise in any one or more of the following areas: quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for

membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations shall include complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: May 20, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-11944 Filed 5-26-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003M-0462]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a

quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified in writing by FDA of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from October 1, 2003, through December 31, 2003. There were no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE OCTOBER 1, 2003, THROUGH DECEMBER 31, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 000023/02003M-0462	MedMira Laboratories, Inc.	MedMira Reveal Rapid HIV-1 Antibody Test	Apr. 16, 2003

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cber/products.htm>.

Dated: May 20, 2004.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 04-11947 Filed 5-26-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration

(FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 27, 2004, from 8 a.m. to 5:30 p.m.

Location: Food and Drug Administration, CDER Advisory