provides that each medical device panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

Nomination Procedures

Consumer Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Nominations shall include a complete curriculum vitae of each nominee 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. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

Industry Representatives

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vitae of each nominee. The term of office is up to 4 years, depending on the appointment date.

Selection Procedures

Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Industry Representatives

Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

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: June 30, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–17794 Filed 7–8–97; 8:45 am]

BILLING CODE 4160–01–F

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 Product Radiation Safety Standards Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and those that will or may occur through June 30, 1998.

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 notice.

ADDRESSES: All nominations and curricula vitae for the device panels should be sent to Nancy J. Pluhowski, Office of Device Evaluation (HFZ–400), CDRH, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

All nominations and curricula vitae for the National Mammography Quality Assurance Advisory Committee, excluding consumer representatives, should be sent to Charles A. Finder, CDRH (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for government and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee should be sent to Orhan Suleiman, CDRH (HFZ–240), (address above).

All nominations and curricula vitae for health professionals, industry representatives, and government representatives for the Device Good Manufacturing Practice Advisory Committee should be sent to Sharon Kalokerinos, CDRH (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

All nominations and curricula vitae for consumer representatives for the National Mammography Quality Assurance Advisory Committee, general public representatives for the Device Good Manufacturing Practice Advisory Committee and the Technical Electronic Product Radiation Safety Standards Committee, should be sent to Annette Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members for vacancies listed below.

1. *Anesthesiology and Respiratory Therapy Devices Panel*: Two vacancies immediately, three vacancies occurring November 30, 1997; 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*: Two vacancies immediately; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

3. *Clinical Chemistry and Clinical Toxicology Devices Panel*: Three vacancies occurring February 28, 1998; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, or oncology.

4. *Dental Products Panel*: Two vacancies immediately, one vacancy occurring October 31, 1997; dentists who have expertise in the areas of lasers, endosseous implants, temporomandibular joint implants, dental materials and/or endodontics; or experts in bone physiology relative to the oral and maxillofacial area.

5. *Ear, Nose, and Throat Devices Panel*: Three vacancies occurring October 31, 1997; audiologists, otolaryngologists, neurophysiologist, statisticians, or electrical or biomedical engineers.

6. *Gastroenterology and Urology Devices Panel*: Three vacancies occurring December 31, 1997; nephrologists with expertise in diagnostic and therapeutic management of adult and pediatric patient populations.

7. *General and Plastic Surgery Devices Panel*: Two vacancies immediately, three vacancies occurring August 31, 1997; general surgeons, plastic surgeons, biomaterials experts, laser experts, wound healing experts or endoscopic surgery experts.

8. *General Hospital and Personal Use Devices Panel*: Five vacancies immediately, two vacancies occurring December 31, 1997; internists, pediatricians, neonatologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

9. *Hematology and Pathology Devices Panel*: One vacancy occurring February 28, 1998; cytopathologists and histopathologists; hematologists (blood banking, coagulation and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

10. *Immunology Devices Panel*: Two vacancies immediately, one vacancy occurring February 28, 1998; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, or clinical laboratory medicine.

11. *Microbiology Devices Panel*: Three vacancies occurring February 28, 1998; infectious disease clinicians; clinical microbiologists with expertise in antimicrobial and antimycobacterial susceptibility testing, chemotherapy and in vitro diagnostic (IVD) applications; clinical virologists with expertise in clinical diagnosis and IVD assays; clinical oncologists experienced with antitumor resistance and susceptibility; and molecular biologists.

12. *Obstetrics and Gynecology Devices Panel*: Three vacancies immediately, two vacancies occurring January 31, 1998; experts in reproductive endocrinology, endoscopy, electrosurgery, laser surgery, assisted reproductive technologies, and contraception; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; and experts in gynecology in the older patient.

13. *Ophthalmic Devices Panel*: Three vacancies occurring October 31, 1997; ophthalmologists specializing in glaucoma, surgical pediatric ophthalmology (experienced in correction of aphakia), retinal diseases or corneal diseases; optometrists with expertise in contact lenses, or specialists in clinical study design.

14. *Orthopedic and Rehabilitation Devices Panel*: Three vacancies immediately, two vacancies occurring August 31, 1997; orthopedic surgeons experienced with prosthetic ligament devices, joint implants, or spinal instrumentation; physical therapists experienced in spinal cord injuries, neurophysiology, electrotherapy, and joint biomechanics; rheumatologists; or biomedical engineers.

15. *Radiological Devices Panel*: One vacancy immediately, two vacancies occurring January 31, 1998; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, mammography, thermography, transillumination, hyperthermia cancer therapy, bone densitometry, magnetic resonance, computed tomography, or ultrasound.

16. *National Mammography Quality Assurance Advisory Committee*: Seven vacancies occurring January 31, 1998; five shall include physicians, practitioners, and other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography; and two shall include consumer representatives from among national breast cancer or consumer health organizations with expertise in mammography.

17. *Device Good Manufacturing Practice Advisory Committee*: Four vacancies occurring May 31, 1998; one government representative, one health professional, one industry representative, and one general public representative.

18. *Technical Electronic Product Radiation Safety Standards Committee*: Five vacancies occurring December 31, 1997; two government representatives, one industry representative, and two general public representatives.

Functions

Medical Devices Panels

The functions of the panels are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in 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 drug panel are to: (1) Evaluate and recommend whether various prescription drug products should be changed to over-the-counter status; and (2) evaluate data and make recommendations concerning the approval of new dental drug products for human use.

National Mammography Quality Assurance Advisory Committee

The functions of the committee are to advise FDA on: (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.

Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacturing, packing, storage, and installation of devices, and make recommendations on the feasibility and reasonableness of the 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, as amended (21 U.S.C. 360(j)), provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government, two shall be representatives of interests of the device manufacturing industry, two shall be representatives of the interests of physicians and other health professionals, and two shall be representatives of the interests of the general public.

Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to advise 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, as amended by the Safe Medical Devices Act of 1990 (21 U.S.C. 360kk(f)), 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.

Qualifications

Medical Device Panels

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 shown above. The term of office is up to 4 years, depending on the appointment date.

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 are shown above. The term of office is up to 4 years, depending on the appointment date.

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 are shown above. The term of office is up to 4 years, depending on the appointment date.

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 are shown above. The term of office is up to 4 years, depending on the appointment date.

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 a 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.

Consumer/General Public Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vitae of each nominee and

shall state 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. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

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: June 30, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–17795 Filed 7–8–97; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 1998. The previous announcement of this program, which was published in the **Federal Register** of June 6, 1996, is superseded by this announcement. In the future, a new announcement will be published annually.

DATES: Application receipt dates are: October 15, 1997, and March 15, 1998. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Park Bldg., rm. 3–40, Rockville, MD 20857, 301–443–6170. (Applications hand-carried or commercially delivered should be addressed to the Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20852.)

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Ronda A. Balham, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 8–73, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA is announcing the anticipated availability of funds for FY 1998 for awarding grants to support clinical trials on the safety and effectiveness of products for a rare disease or condition (i.e., one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Contingent on availability of FY 1998 funds, it is anticipated that $11.3 million will be available, of which 3.5 million will be for noncompeting continuation awards. This will leave $7.8 million for funding approximately 30 new applications. Any phase clinical trial is eligible for up to $100,000 in direct costs per annum plus applicable indirect costs for up to 3 years. Phase 2 and 3 clinical trials are eligible for up to $200,000 in direct costs per annum plus applicable indirect costs for up to 3 years.

FDA will support the clinical studies covered by this notice under section 301 of the Public Health Service Act (the PHS act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free work place and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit work plans that address specific objectives of ''Healthy People 2000.'' Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, stock No. 017–001–00474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

PHS policy is that applicants for PHS clinical research grants are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

I. Program Research Goals

OPD was established to identify and facilitate the availability of orphan products. In the OPD grant program, orphan products are defined as drugs, biologics, medical devices, and foods for medical purposes which are indicated for a rare disease or condition (i.e., one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is lower than 200,000 per annum.

One way to make orphan products available is to support clinical research to determine whether the products are safe and effective. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder. The grants are funded under the legislative authority of section 301 of the PHS Act (42 U.S.C 241).

The goal of FDA's OPD grant program is the clinical development of products for use in rare diseases or conditions where no current therapy exists or where current therapy would be improved. FDA provides grants to conduct clinical studies intended to provide data acceptable to the agency which will either result in or substantially contribute to approval of these products. Applicants should keep this goal in mind and must include an explanation in the ''Background and Significance'' section of the application of how their proposed study will either facilitate product approval or provide essential data needed for product development. Information regarding meetings and/or discussions with FDA reviewing division staff about the product to be studied should also be provided as an appendix to the application. This information is extremely important for the review process.

Except for medical foods that do not require premarket approval, FDA will only consider awarding grants to support clinical studies for determining whether the products are safe and