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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, 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 for those that will or may occur through August 31, 2000.

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, Advisory Panel Coordinator, 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 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 H. Suleiman, CDRH (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for general public representatives for 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, CDRH (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. *Circulatory System Devices Panel:* Three vacancies occurring June 30, 2000; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

2. *Clinical Chemistry and Clinical Toxicology Devices Panel:* Three vacancies occurring February 28, 2000; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, endocrinology or oncology.

3. *Dental Products Panel:* One vacancy immediately, one vacancy occurring October 31, 1999; 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.

4. *Ear, Nose, and Throat Devices Panel*: One vacancy occurring October 31, 1999; audiologists, otolaryngologists, neurophysiologist, statisticians, or electrical or biomedical engineers.

5. *General and Plastic Surgery Devices Panel*: One vacancy immediately; general surgeons, plastic surgeons, biomaterials experts, laser experts, wound healing experts or endoscopic surgery experts.

6. *General Hospital and Personal Use Devices Panel*: One vacancy immediately, one vacancy occurring December 31, 1999; internists, pediatricians, neonatologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

7. *Hematology and Pathology Devices Panel*: Two vacancies occurring February 28, 2000; cytopathologists and histopathologists; hematologists (blood banking, coagulation and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

8. *Immunology Devices Panel*: Three vacancies occurring February 28, 2000; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

9. *Microbiology Devices Panel*: One vacancy occurring February 28, 2000; infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease (STD) specialists, pediatric infectious disease specialists; clinical microbiologists; clinical microbiology laboratory directors, clinical virologists with expertise in clinical diagnosis and in vitro diagnostic (IVD) assays, e.g., hepatologists; molecular biologists; and clinical oncologists experienced with antitumor resistance and susceptibility.

10. *Obstetrics and Gynecology Devices Panel*: One vacancy occurring January 31, 2000; 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.

11. *Ophthalmic Devices Panel*: One vacancy occurring October 31, 1999; ophthalmologists specializing in refractive surgery, vitreo-retinal surgery, and the treatment of glaucoma; vision scientists and electrophysiologists.

12. *Orthopaedic and Rehabilitation Devices Panel*: One vacancy immediately; one vacancy occurring August 31, 2000; doctors of medicine or philosophy with experience in tissue engineering, calcification or biomaterials; 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.

13. *Radiological Devices Panel*: Two vacancies occurring January 31, 2000; 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.

14. *National Mammography Quality Assurance Advisory Committee*: Three vacancies occurring January 31, 2000; physicians, practitioners, and other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.

15. *Technical Electronic Product Radiation Safety Standards Committee*: Five vacancies occurring December 31, 1999; 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.

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.

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.

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

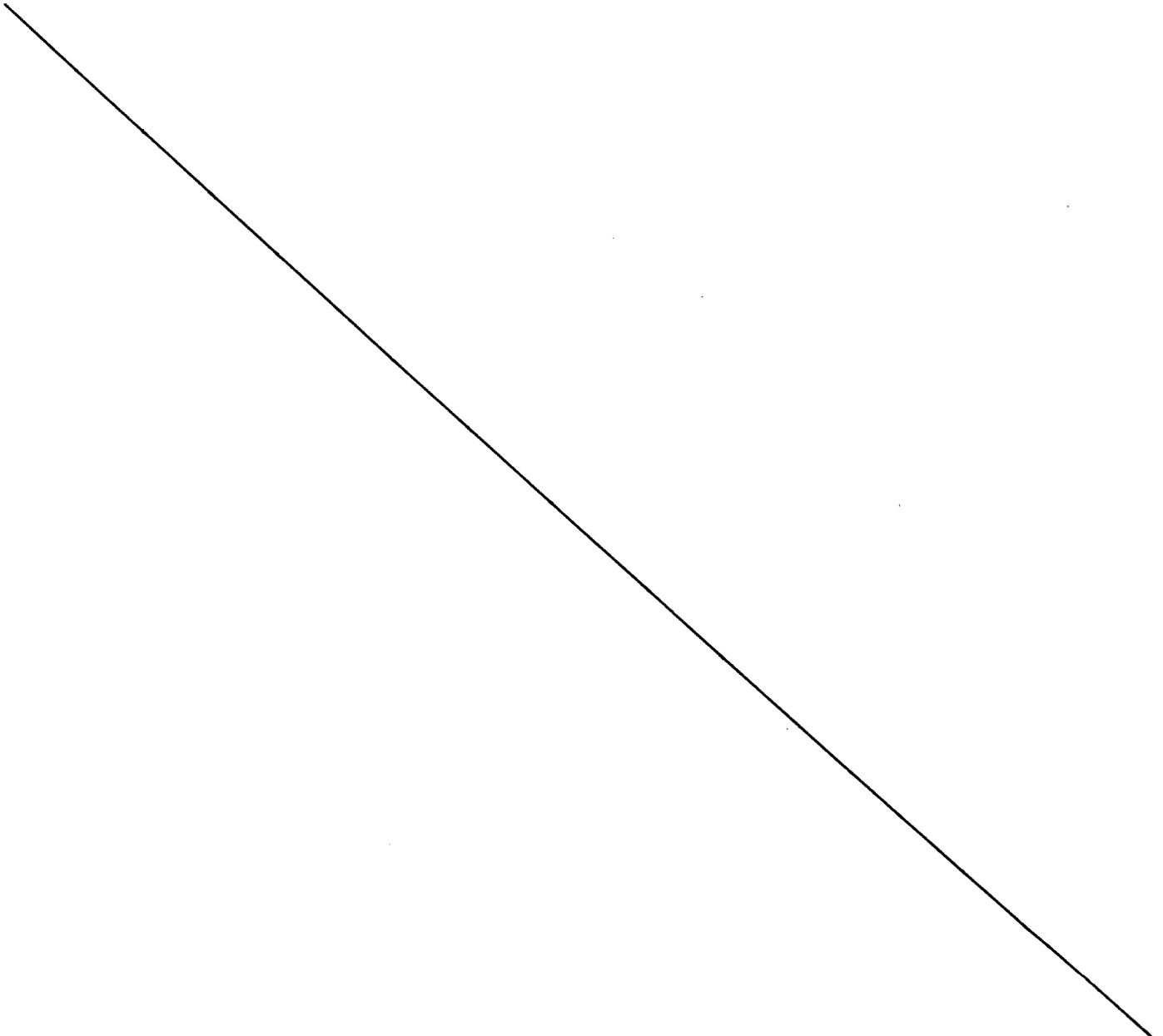
Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall 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 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.

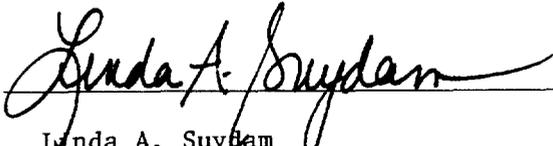
Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and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

Nominations shall include a complete curriculum vita 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 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: September 30, 1999



Linda A. Suydam
Senior Associate Commissioner

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