

Request for Nominations for Voting Members on Public Advisory Panels or Committees in the Center for Devices and Radiological Health

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 and on the National Mammography Quality Assurance Advisory 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, 1997.

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 panels should be sent to Nancy J. Pluhowski, Office of Device Evaluation (HFZ-400), Center for Devices and Radiological Health, 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 K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

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:* One vacancy occurring November 30, 1996; 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 occurring June 30, 1997; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

3. *Dental Products Panel:* Two vacancies occurring October 31, 1996; dentists who have experience with lasers, endosseous implants, and temporomandibular joint implants; or experts in bone physiology relative to the oral and maxillofacial area.

4. *Gastroenterology and Urology Devices Panel:* Three vacancies immediately; nephrologists, urologists, and gastroenterologists with expertise in diagnostic and therapeutic management of adult and pediatric patient populations.

5. *General and Plastic Surgery Devices Panel:* One vacancy immediately, one vacancy occurring August 31, 1996; 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, four vacancies occurring December 31, 1996; 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, 1997; cytopathologists and histopathologists; hematologists (blood banking, coagulation, and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

8. *Immunology Devices Panel:* Three vacancies immediately, two vacancies occurring February 28, 1997; persons with experience in medical, surgical, or clinical oncology, internal medicine,

clinical immunology, allergy, or clinical laboratory medicine.

9. *Microbiology Devices Panel:* Two vacancies occurring February 28, 1997; infectious disease clinicians; clinical microbiologists with expertise in antimicrobial and antimycobacterial susceptibility testing and chemotherapy; clinical virologists with expertise in diagnosis and assays; clinical oncologists experienced with antitumor resistance and susceptibility; and molecular biologists.

10. *Neurological Devices Panel:* Two vacancies occurring November 30, 1996; neurologists, epileptologists, biomedical engineers, interventional neuroradiologists, neurosurgeons with interest in medical devices, or persons experienced with neurological devices with a strong background in biostatistics.

11. *Obstetrics and Gynecology Devices Panel:* Two vacancies immediately, one vacancy occurring January 31, 1997; experts in reproductive endocrinology, endoscopy, electrosurgery, laser surgery, assisted reproductive technologies, and contraception.

12. *Ophthalmic Devices Panel:* One vacancy immediately, one vacancy occurring October 31, 1996; 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.

13. *Orthopedic and Rehabilitation Devices Panel:* Two vacancies immediately; 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.

14. *Radiological Devices Panel:* One vacancy occurring January 31, 1997; 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.

15. *National Mammography Quality Assurance Advisory Committee*: Five vacancies immediately, six vacancies occurring January 31, 1997; physicians, practitioners, and other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.

Functions

Medical Device 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; (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 advisory 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; (2) evaluate data and make recommendations concerning the approval of new dental drug products for human use; (3) evaluate data and make recommendations concerning drug products that may also be cosmetics; and (4) using a Plaque Subcommittee, review and evaluate data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed dental drug products for human use, and the adequacy of their labeling. The subcommittee will advise on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

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 or other requirements 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.

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. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise. The particular needs for this committee 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 the National Mammography Quality Assurance Advisory Committee. 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.

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: August 13, 1996.

Michael A. Friedman,
Deputy Commissioner for Operations.
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Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a