

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 professional, 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:* Four vacancies immediately, one vacancy occurring November 30, 2003; 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. *Clinical Chemistry and Clinical Toxicology Devices Panel:* Three vacancies occurring February 28, 2004; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, and/or clinical laboratory medicine.

4. *Dental Products Panel:* Two vacancies immediately, three vacancies occurring October 31, 2003; dentists, engineers and scientists who have expertise in the areas of lasers,

temporomandibular joint implants and/or endodontics; or experts in tissue engineering and/or bone physiology relative to the oral and maxillofacial area.

5. *General and Plastic Surgery Devices Panel:* Four vacancies immediately, one vacancy occurring August 31, 2003; 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. *Hematology and Pathology Devices Panel:* Three vacancies immediately; 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.

7. *Immunology Devices Panel:* Three vacancies occurring February 28, 2004; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

8. *Molecular and Clinical Genetics Devices Panel:* Four vacancies occurring May 31, 2004; experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. The agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics as well as ancillary fields of study will be considered.

9. *Obstetrics and Gynecology Devices Panel:* One vacancy occurring January 31, 2004; experts in perinatology, embryology, reproductive endocrinology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, post-operative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; expert in gynecology in the older patient; experts in diagnostic (optical) spectroscopy.

10. *Ophthalmic Devices Panel:* One vacancy occurring October 31, 2003; ophthalmologists specializing in cataract and refractive surgery, vitreo-retinal surgery, pediatric

ophthalmology, and the treatment of glaucoma; in addition to vision scientists, electrophysiologists, and optometrists.

11. *Orthopaedic and Rehabilitation Devices Panel:* Two vacancies occurring August 31, 2004; 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.

12. *Radiological Devices Panel:* One vacancy immediately, two vacancies occurring January 31, 2004; statistician with biomedical expertise including the design of clinical trials, ROC (receiver operating characteristic) analysis, diagnostic test evaluation, and data testing.

13. *National Mammography Quality Assurance Advisory Committee:* Three vacancies occurring January 31, 2004; physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.

14. *Device Good Manufacturing Practice Advisory Committee:* six vacancies occurring immediately; three government representatives, two industry representatives, and one health professional.

15. *Technical Electronic Product Radiation Safety Standards Committee:* Four vacancies immediately, one government representative and three industry representatives; three vacancies occurring December 31, 2003, 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: (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