2. Circulatory System Devices Panel: Three vacancies occurring June 30, 1995; 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, 1996; 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 occurring October 31, 1995; dentists who have experience with lasers, endosseous implants, and temporomandibular joint implants; or experts in bone physiology relative to the oral and maxillofacial area.

5. Ear, Nose, and Throat Devices Panel: One vacancy occurring October 31, 1995; audiologists, otolaryngologists, neurophysiologists, statisticians, or electrical or biomedical engineers.

6. Gastroenterology and Urology Devices Panel: Three vacancies occurring December 31, 1995; nephrologists, urologists, and gastroenterologists with expertise in diagnostic and therapeutic management of adult and pediatric patient

populations.

7. Hematology and Pathology Devices Panel: One vacancy occurring February 28, 1996; cytopathologists and histopathologists; hematologists (blood banking, coagulation, and hemostatis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

8. Immunology Devices Panel: Two vacancies occurring February 28, 1996; medical or surgical oncologists experienced with tumor markers, or

clinical immunologists.

9. Microbiology Devices Panel: One vacancy occurring February 28, 1996; 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, 1995; neurologists, 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: One vacancy occurring January

31, 1996; experts in reproductive endocrinology, endoscopy, electrosurgery, laser surgery, assisted reproductive technologies, and contraception.

12. Ophthalmic Devices Panel: Two vacancies occurring October 31, 1995; ophthalmologists specializing in glaucoma, surgical pediatric ophthalmology (experienced in correction of aphakia), retinal diseases or corneal diseases; and optometrists with expertise in contact lenses.

13. Orthopedic and Rehabilitation Devices Panel: One vacancy occurring August 31, 1995; 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, 1996; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, mammography, thermography, transillumination, hyperthermia, bone densitometry, magnetic resonance, computed tomography, or ultrasound.

15. National Mammography Quality Assurance Advisory Committee: Four vacancies occurring January 31, 1996; 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 panel. The functions of the drug panel are to: (1) Evaluate and recommend whether various prescription drug products should be changed to over-thecounter 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; and (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities.

The committee will also determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and the effects of personnel or other requirements on access to the services of such facilities in such areas; whether there will exist a sufficient number of medical physicists after October 1, 1999, and 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