TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					793,308

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–18130 Filed 7–19–01; 8:45 am]

BILLING CODE 4160–01–S

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 Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2002.

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), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, e-mail: NJP@CDRH.FDA.GOV.

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

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

All nominations and curricula vitae for government representatives and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee should be sent to Orhan Suleiman, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for consumer representatives for the National Mammography Quality Assurance Advisory Committee, and general public representatives for the Device Good Manufacturing Practice Advisory Committee and the Technical Electronic Product Radiation Safety Standards Committee should be sent to Maureen Hess, Office of Consumer Affairs (HFE–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: MHESS@OC.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: FDA is requesting nominations of voting members for vacancies listed below.

1. *Anesthesiology and Respiratory Therapy Devices Panel*: Two vacancies occurring November 30, 2001; 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. *Dental Products Panel*: Two vacancies immediately; dentists 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.

4. *Ear, Nose, and Throat Devices Panel*: Three vacancies occurring October 31, 2001; otologists, neurotologists, audiologists, hearing scientists, and electrophysiologists.

5. *Gastroenterology and Urology Devices Panel*: Three vacancies occurring December 31, 2001; urologists, gastroenterologists, and biostatisticians.

6. *General and Plastic Surgery Devices Panel*: Three vacancies immediately, three vacancies occurring August 31, 2002; general surgeons, plastic surgeons, biomaterials experts, laser experts, wound healing experts or endoscopic surgery experts.

7. *General Hospital and Personal Use Devices Panel*: Four vacancies immediately, three vacancies occurring December 31, 2001; internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

8. *Immunology Devices Panel*: One vacancy occurring February 28, 2002; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

9. *Medical Devices Dispute Resolution Panel*: One vacancy immediately;

experts with broad, cross-cutting scientific, clinical, analytical or mediation skills.

10. *Microbiology Devices Panel*: Two vacancies occurring February 28, 2002; infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, mycologists; clinical microbiologists; clinical microbiology laboratory directors, and clinical virologists with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists.

11. *Neurological Devices Panel*: Three vacancies occurring November 30, 2001; neurosurgeons (cerebrovascular and pediatric), neurologists (pain management and movement disorders), interventional neuroradiologists, or biostatisticians.

12. *Obstetrics and Gynecology Devices Panel*: Two vacancies occurring January 31, 2002; experts in perinatology, embryology, reproductive endocrinology, operative hysteroscopy, pelviscopy, 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. *Orthopaedic and Rehabilitation Devices Panel*: Five vacancies immediately; 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.

14. *Radiological Devices Panel*: One vacancy immediately, two vacancies occurring January 31, 2002; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, radiation physics, mammography, thermography, transillumination, hyperthermia cancer therapy, bone densitometry, magnetic resonance imaging, computed tomography, ultrasound imaging, statistical analysis, digital imaging and image processing, or computer-aided detection and diagnosis.

15. *National Mammography Quality Assurance Advisory Committee*: Four vacancies occurring January 31, 2002; two 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.

16. *Device Good Manufacturing Practice Advisory Committee*: Three vacancies occurring May 31, 2002; one government representative, one industry representative, and one general public representative.

17. *Technical Electronic Product Radiation Safety Standards Committee*: Five vacancies occurring December 31, 2001, two government representatives, one industry representative, and two general public representatives.

Functions

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, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to 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 dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or agency decisions or actions.

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 promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those 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 (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) 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 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

Panels of the Medical Devices Advisory Committee

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 that include use of a consortium of consumer organizations that 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: July 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education (CHGME) Payment Program: Final Methodology for Determination of FTE Resident Count, Treatment of New Children's Teaching Hospitals, and Calculation of Indirect Medical Education Payment

AGENCY: Health Resources and Services Administration, HHS.