Export of Medical Devices—Foreign Letters of Approval—Federal Food, Drug, and Cosmetic Act—21 U.S.C. 381(e)(2) (OMB Control No. 0910 0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. FDA uses the written authorization from the foreign country to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

In the **Federal Register** of June 20, 2000 (65 FR 38288), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Statute	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act	20	1	20	2.5	50
Total					50

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

These estimates are based on the experience of FDA's medical device program personnel, who estimate that completion of the requirements of this collection of information should take approximately 2.5 hours to complete. Prior to the enactment of the Food and Drug Export Reform and Enhancement Act of 1996, FDA received approximately 800 requests from U.S. firms to export medical devices under section 801(e)(2) of the act. The enactment of the Food and Drug Export Reform and Enhancement Act of 1996 has greatly reduced the number of export permit requests made to the present estimated 20 per year.

Dated: September 5, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–23326 Filed 9–11–00; 8:45 am]

BILLING CODE 4160–01–F

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 and 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 August 31, 2001.

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, excluding consumer representatives, 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 consumer representatives for the National Mammography Quality Assurance Advisory Committee should be sent to Mary C. Wallace, Office of Consumer Affairs (HFE–3), 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, (KLW@CDRH.FDA.GOV).

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members for vacancies listed below.

1. *Anesthesiology and Respiratory Therapy Devices Panel:* Three vacancies occurring November 30, 2000; 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 immediately, two vacancies occurring June 30, 2001; 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, 2000; 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:* One vacancy immediately, two vacancies occurring October 31, 2000; audiologists, otolaryngologists, neurophysiologists, statisticians, or electrical or biomedical engineers.

5. *Gastroenterology and Urology Devices Panel:* One vacancy immediately, two vacancies occurring December 31, 2000; nephrologists with expertise in diagnostic and therapeutic management of adult and pediatric patient populations.

6. *General and Plastic Surgery Devices Panel:* One vacancy immediately, two vacancies occurring August 31, 2001; general surgeons, plastic surgeons, biomaterials experts, laser experts, wound healing experts or endoscopic surgery experts.

7. *General Hospital and Personal Use Devices Panel:* Two vacancies immediately, two vacancies occurring December 31, 2000; internists, pediatricians, neonatologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

8. *Hematology and Pathology Devices Panel:* Two vacancies immediately, one vacancy occurring February 28, 2001; cytopathologists and histopathologists, hematologists (blood banking, coagulation and hemostasis), molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

9. *Immunology Devices Panel:* Two vacancies occurring February 28, 2001; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.

10. *Microbiology Devices Panel:* Two vacancies occurring February 28, 2001; infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists; clinical microbiologists; clinical microbiology laboratory directors, clinical virologists with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists; and clinical oncologists experienced with antitumor resistance and susceptibility.

11. *Neurological Devices Panel:* Two vacancies occurring November 30, 2000; neurologists with experience in pain management and the treatment of movement disorders, neurosurgeons with experience in pediatric and stereotactic neurosurgery, interventional neuroradiologists, biomedical engineers, or biostatisticians with interest in neurological devices.

12. *Obstetrics and Gynecology Devices Panel:* Two vacancies occurring January 31, 2001; 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.

13. *Ophthalmic Devices Panel:* Three vacancies occurring October 31, 2000; ophthalmologists specializing in refractive surgery, vitreo-retinal surgery, and the treatment of glaucoma; vision scientists, electrophysiologists and optometrists.

14. *Orthopaedic and Rehabilitation Devices Panel:* One vacancy immediately; one vacancy occurring August 31, 2000; five vacancies occurring August 31, 2001; 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.

15. *Radiological Devices Panel:* One vacancy occurring January 31, 2001; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, radiation physics, mammography, thermography, transillumination, hyperthermia cancer therapy, bone densitometry, magnetic resonance, computed tomography, or ultrasound.

16. *National Mammography Quality Assurance Advisory Committee:* One vacancy immediately; six vacancies occurring January 31, 2001; five 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.

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.

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.

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 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 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: September 1, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–23325 Filed 9–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifiers: HCFA–R–267 (OMB #0938–0753)]

Intent of Clearance: Public Information Collection Meeting To Discuss Requirements To Be Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, in the near future, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), will be submitting to the Office of Management and Budget (OMB) a request for review of the proposed Appeals Data Collections System for Managed Care Organizations (M+COs)

In order to seek public input at this early juncture and before we seek approval for this information collection from OMB, HCFA will be holding a town hall meeting to discuss the goals of the proposed Appeals Data Collection System for M+COs, issues that may surround it, and the required data elements associated with it.

Interested persons are invited to participate in a public discussion about various aspects of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dates: The meeting is scheduled for September 25, 2000 from 10 a.m. until 4 p.m., E.D.T.

Persons Interested in Attending or Requesting More Information Should Contact

Brandon Bush, (410) 786–0028 (*Bbush@HCFA.GOV*) Project Coordinator; John Burke , (410) 786–1325 (*JBurke1@HCFA.GOV*) PRA Reports Clearance Officer.

SUPPLEMENTARY INFORMATION:

Background

At present, we capture data on ''plan level'' appeal activities at the Medicare $^{+}$ Choice Organizations (M^{+}COs), namely those managed care appeals not resolved at the M^{+}CO level and which