TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for designation as U.S. CAB	12	1	12	24	288
Premarket reports by EC CAB's	20	5	100	40	4,000
Quality system reports by EC CAB's	20	5	100	32	3,200
Total					7,488

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Records of evaluation of premarket submissions by EC CAB's	20	5	100	10	1,000
Records of evaluation of quality systems	20	5	100	10	1,000
Total					2,000

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

The burdens are explained as follows:

II. Reporting

A. Requests for Designation as U.S. CAB

Under this program, U.S. firms may apply for designation as a U.S. CAB. Such designation will enable that firm to perform third-party evaluations of U.S. products for export to the EC. Likewise, European firms may apply to be designated as EC CAB's, which will enable them to perform third-party evaluations of products to be exported to the United States. The application for nomination as an EC CAB does not represent a paperwork burden subject to the PRA because the designation procedure is an internal process which is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. The agency anticipates, based on discussions with the National Institute of Science and Technology of the U.S. Department of Commerce and officials of other standards organizations, that approximately 12 applications for designation as U.S. CAB's will be received.

B. Premarket Reports

Under this program, EC CAB's will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EC CAB's would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluation for approximately 100 medical device products annually. The agency further estimates, based on dialogue with EC officials, that 20 firms will be designated to act as EC CAB's.

C. Quality System Reports

Under this program, EC CAB's will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EC CAB's would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluations for approximately 100 medical device products annually. The agency estimates that 20 EC CAB's will perform these evaluations.

III. Recordkeeping

As stated previously, firms designated as EC CAB's will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such evaluation will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each evaluation. The agency anticipates that 100 premarket reports and 100 quality system reports will be generated and required to be maintained by EC CAB's annually. Thus, the agency estimates that 100 records of evaluations of quality systems and premarket submissions will be retained by the designated EC CAB's. Based on experience with the Third Party Review Pilot Program, which was announced in the **Federal Register** of April 3, 1996 (61 FR 14789), the agency anticipates that each recordkeeper will require no more than 2 hours of recordkeeping per review. The agency is estimating 5 reviews per respondent; therefore, the total number of hours per recordkeeper is 10.

Dated: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17602 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests 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 nonvoting consumer representatives and nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through June 30, 1999.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore,

encourages nominations for appropriately qualified candidates from these groups, as well as nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations should be received by (*insert date 30 days after date of publication in the* **Federal Register**), for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae for consumer representatives should be submitted in writing to Annette J. Funn (address below). All nominations and curricula vitae (which includes nominee's office address and telephone number) for industry representatives should be submitted in writing to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding consumer representatives: Annette Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5006.

Regarding industry representatives: Kathleen L. Walker, Office of Systems and Management (HFZ–17), CDRH, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting members representing consumer and industry interests for the vacancies listed below:

Medical Devices Panels	Approximate Date Representative is Needed	
	Consumer	Industry
Circulatory System Devices Panel	July 1, 1999	NV
Immunology Devices Panel	March 1, 1999	NV
Obstetrics and Gynecology Devices Panel	NV	February 1, 1999

NV = No vacancy

Function

The functions of the medical device 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.

Consumer and Industry Representation

Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

Nomination Procedures

Consumer 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. Self-nominations are also accepted. 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.

Nominations shall include a complete curriculum vitae 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 panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

Industry Representatives

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vitae of each nominee. The term of office is up to 4 years, depending on the appointment date.

Selection Procedures

Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which 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.

Industry Representatives

Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in

participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

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: June 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–17601 Filed 7–1–98; 8:45 am]

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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 Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Product Radiation Safety Standards 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, 1999.

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, Office of Device Evaluation (HFZ–400), CDRH, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

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

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

All nominations and curricula vitae for general public representatives for the Device Good Manufacturing Practice Advisory Committee and the Technical Electronic Product Radiation Safety Standards Committee should be sent to Annette Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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. *Circulatory System Devices Panel*: Two vacancies occurring June 30, 1999; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

2. *Clinical Chemistry and Clinical Toxicology Devices Panel*: One vacancy occurring February 28, 1999; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, or oncology.

3. *Dental Products Panel*: Three vacancies immediately, one vacancy occurring October 31, 1998; dentists who have expertise in the areas of lasers, endosseous implants, temporomandibular joint implants, dental materials and/or endodontics; or experts in bone physiology relative to the oral and maxillofacial area.

4. *Ear, Nose, and Throat Devices Panel*: One vacancy occurring October 31, 1998; audiologists, otolaryngologists, neurophysiologist, statisticians, or electrical or biomedical engineers.

5. *General Hospital and Personal Use Devices Panel*: Three vacancies immediately, one vacancy occurring December 31, 1998; internists, pediatricians, neonatologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

6. *Hematology and Pathology Devices Panel*: Two vacancies occurring February 28, 1999; cytopathologists and histopathologists; hematologists (blood banking, coagulation and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

7. *Immunology Devices Panel*: One vacancy immediately, one vacancy occurring February 28, 1999; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, human genetics testing or clinical laboratory medicine.

8. *Microbiology Devices Panel*: Three vacancies immediately, one vacancy occurring February 28, 1999; infectious disease clinicians; clinical microbiologists with expertise in antimicrobial and antimycobacterial susceptibility testing, chemotherapy and in vitro diagnostic (IVD) applications; clinical virologists with expertise in clinical diagnosis and IVD assays; clinical oncologists experienced with antitumor resistance and susceptibility; and molecular biologists.

9. *Obstetrics and Gynecology Devices Panel*: Two vacancies occurring January 31, 1999; 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.

10. *Orthopaedic and Rehabilitation Devices Panel*: Two vacancies occurring August 31, 1998; 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.

11. *Radiological Devices Panel*: Two vacancies occurring January 31, 1999; 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.

12. *Device Good Manufacturing Practice Advisory Committee*: Four vacancies immediately, one government representative, one health professional, one industry representative, and one general public representative; five