Request for Nominations for 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 consumer and industry representatives to serve on certain device panels of the Medical Devices Advisory Committee and on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and for those that will or may occur through February 28, 1996.

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 May 1, 1995.

ADDRESSES: All nominations and curricula vitae for industry representatives shall be submitted in writing to Kathleen L. Walker (address below). All nominations and curricula vitae for consumer representatives shall be submitted in writing to Martha F. Waugh (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding industry representatives: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6932.

Regarding consumer interests: Martha F. Waugh, Office of Consumer Affairs (HFE–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5006.

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

Committee or Panel	Approximate Date Representative is Needed	
	Consumer	Industry
Clinical Chemistry and Clinical Toxicology Devices Panel	NV	February 28, 1996
Dental Products Panel:		
Drugs	NV	October 31, 1995
Cosmetics	NV	October 31, 1995
Ear, Nose, and Throat Devices Panel	October 31, 1995	NV
Gastroenterology and Urology Devices Panel	NV	December 31, 1995
General and Plastic Surgery Devices Panel	NV	August 31, 1995
Hematology and Pathology Devices Panel	February 28, 1996	February 28, 1996
Microbiology Devices Panel	NV	February 28, 1996
Orthopedic and Rehabilitation Devices Panel	August 31, 1995	NV
Radiological Devices Panel	January 31, 1996	NV
National Mammography Quality Assurance Advisory Committee	January 31, 1996	NA

NV = No vacancy
NA = Not applicable

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-the-counter 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 the 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 the Food and Drug Administration 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; and whether there will exist a sufficient number of medical physicists after October 1, 1999, and the costs and benefits of compliance with these requirements.

Consumer and Industry Representation

Medical Device Panels

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.

National Mammography Quality Assurance Advisory Committee

Section 354n of the Public Health Service Act (42 U.S.C. 263b), as amended by the Mammography Quality Standards Act of 1992, provides that at least four of the individuals nominated for membership should be from among national breast cancer or consumer health organizations with expertise in mammography. The committee may include one technically qualified member who is identified with consumer interests.

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 industrial 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: February 21, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–4911 Filed 2–28–95; 8:45 am]

BILLING CODE 4160–01–F

Request for Nominations for Voting Members on Public Advisory Panels or Committees in the Center for Devices and Radiological Health

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 on 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 vacancies that will or may occur through February 28, 1996.

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 panels should be sent to Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

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

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6932.

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

1. *Anesthesiology and Respiratory Therapy Devices Panel*: One vacancy occurring November 30, 1995; general anesthesiologists, anesthesiologists specializing in regional anesthesia, physicians with expertise in ventilatory support, or nurse anesthetists.