

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