

4. *Anti-Infective Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

5. *Anti-Viral Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

6. *Arthritis Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

7. *Cardiovascular and Renal Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

8. *Dermatologic and Ophthalmic Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of dermatologic and ophthalmic disorders.

9. *Drug Safety and Risk Management Advisory Committee (formerly Drug Abuse Advisory Committee)*

Advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with the regard to safety, efficacy, and abuse potential, risk management, risk communication and quantitative evaluation of spontaneous reports, and recommends actions to be taken by the Food and Drug Administration with regard to marketing, investigation and control of such drugs or other substances.

10. *Endocrinologic and Metabolic Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

11. *Gastrointestinal Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal disorders.

12. *Nonprescription Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of the over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

13. *Oncologic Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for the use in the treatment of cancer.

14. *Peripheral and Central Nervous System Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic disease.

15. *Psychopharmacologic Drug Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

16. *Pulmonary-Allergy Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (*see FOR FURTHER INFORMATION CONTACT*) within 30 days of publication of this document. Within the subsequent 15 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer

with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for that committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from drug manufacturing industry.

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: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of 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 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 July 31, 2004.

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 for vacancies listed in this notice should be received by July 7, 2003.

ADDRESSES: All nominations and curricula vitae (which includes nominee's office address, telephone number and e-mail address) for industry representatives should be submitted in writing to 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, e-mail: klw@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed as follows:

| Medical Devices Panels | Approximate Date Representative Is Needed |
|--|---|
| Clinical Chemistry and Clinical Toxicology | Mar. 1, 2004 |
| Gastroenterology and Urology | Jan. 1, 2004 |
| General and Plastic Surgery | Sept. 1, 2003 |
| Hematology and Pathology | Mar. 1, 2004 |
| Microbiology | Mar. 1, 2004 |
| Molecular and Clinical Genetics | June 1, 2004 |
| Radiological | Feb. 1, 2004 |

I. Functions

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 (the 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.

II. Industry Representation

Section 520(f)(3) of 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 interests of the medical device manufacturing industry.

III. Nomination Procedure

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 vita of each nominee. The term of office is up to 4 years, depending on the appointment date.

IV. Selection Procedure

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: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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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 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, 2004.

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: Send all nominations and curricula vitae to:

1. *For the device panels:* Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2022, e-mail: NJP@CDRH.FDA.GOV.