

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.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**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,

oc03157

DME  
Display Date \_\_\_\_\_  
Publication Date \_\_\_\_\_  
Certifier SPKX

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 Gastroenterology and Urology General and Plastic Surgery Hematology and Pathology Microbiology Molecular and Clinical Genetics Radiological	Mar 1, 2004 Jan 1, 2004 Sept. 1, 2003 Mar 1, 2004 Mar. 1, 2004 June 1, 2004 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.

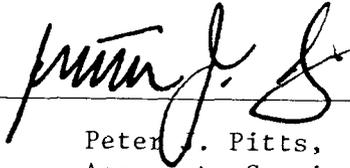
### **IV. Selection Procedure**

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: 5/29/03

May 29, 2003.

  
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Peter J. Pitts,  
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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