

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements To Conduct Studies of Illnesses Among Persian Gulf War Veterans, Program Announcement 748: Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreements to Conduct Studies of Illnesses Among Persian Gulf War Veterans, Program Announcement 748.

Time and Date: 8:30 a.m.-4:30 p.m., August 12, 1997, 8:30 a.m.-4:30 p.m., August 13, 1997.

Place: Lenox Inn, 3387 Lenox Road, Atlanta, Georgia 30326.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 748.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Contact Person for More Information: Phillip M. Talboy, Deputy Chief, Veterans'

Health Activity Working Group, National Center for Environmental Health, CDC, M/S F28, 4770 Buford Highway, NE, Atlanta, Georgia 30341, telephone 770/488-7300.

Dated: July 2, 1997.

**Carolyn J. Russell,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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**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. Nominations will be accepted for current vacancies and for those that will or may occur through June 30, 1998.

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 August 8, 1997, 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 J. 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, 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 for nonvoting members representing consumer and industry interests for the vacancies listed below:

Medical Devices Panels	Approximate Date Representative is Needed	
	Consumer	Industry
Anesthesiology and Respiratory Therapy Devices Panel	December 1, 1997	December 1, 1997
Clinical Chemistry and Clinical Toxicology Devices Panel	March 1, 1998	NV
Dental Products Panel (Medical Devices)	NV	November 1, 1997
General Hospital and Personal Use Devices Panel	NV	January 1, 1998
Microbiology Devices Panel	March 1, 1998	NV
Ophthalmic Devices Panel	NV	November 1, 1997

NV = No vacancy

**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; (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 30, 1997.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 97-17794 Filed 7-8-97; 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 National Mammography Quality Assurance 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, 1998.

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 the National Mammography Quality Assurance Advisory Committee, excluding consumer representatives, should be sent to Charles A. Finder, CDRH (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., 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), (address above).

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 consumer representatives for the National Mammography Quality Assurance Advisory Committee, 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