

manufacturing industry. The Agency is requesting nominations for nonvoting industry representatives to certain panels identified in the following paragraphs.

#### **I. Functions of MDAC**

(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 (the Commissioner) 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 FD&C 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.

##### **A. Clinical Chemistry and Clinical Toxicology Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including clinical toxicology, clinical chemistry, endocrinology, and oncology, and makes appropriate recommendations to the Commissioner.

##### **B. Ear, Nose, and Throat Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of market and investigational ear, nose, and throat devices, and makes appropriate recommendations to the Commissioner.

##### **C. Medical Devices Dispute Resolution Panel**

Provides advice to the Center Director on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to Agency decisions or actions.

##### **D. Microbiology Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including microbiology, virology, and infectious disease, and makes appropriate recommendations to the Commissioner.

##### **E. Molecular and Clinical Genetics Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including clinical and molecular genetics, and makes appropriate recommendations to the Commissioner.

##### **F. Orthopaedic and Rehabilitation Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices, and makes appropriate recommendations to the Commissioner.

##### **G. Radiological Devices Panel**

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational diagnostic or therapeutic radiological and nuclear medicine devices and makes appropriate recommendations to the Commissioner.

#### **II. Qualifications**

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers or have similar appropriate ties to industry.

#### **III. 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 (see **DATES**). Within the subsequent 30 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 device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner will select the nonvoting member to represent industry interests.

#### **IV. Application Procedure**

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the panel. (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 the device 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: October 26, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-28224 Filed 10-31-11; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2011-N-0002]**

### **Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the National Mammography Quality Assurance Advisory Committees**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) in the Center for Devices and Radiological Health notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by December 1, 2011, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by December 1, 2011.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Margaret J. Ames (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Margaret J. Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5234, Silver Spring, MD 20993, (301) 796-5960, email: [margaret.ames@fda.hhs.gov](mailto:margaret.ames@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

The Mammography Quality Standards Reauthorization Act of 2004 (Pub. L. 108-365) requires the addition of at least two industry representatives with expertise in mammography equipment to the NMQAAC. The Agency is requesting nominations for nonvoting industry representatives on the NMQAAC.

**I. NMQAAC**

Advise FDA 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; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health

professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

**II. Qualifications**

Persons nominated for membership as an industry representative on the NMQAAC must meet the following criteria: (1) Demonstrate expertise in mammography equipment and (2) be able to discuss equipment specifications and quality control procedures affecting mammography equipment. The industry representative must be able to represent the industry perspective on issues and actions before the advisory committee, serve as liaison between the committee and interested industry parties, and facilitate dialogue with the advisory committee on mammography equipment issues.

**III. Selection Procedure**

Any industry organization interested in participating in the selection of appropriate nonvoting members 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 (see **DATES**). Within the subsequent 30 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 candidates, within 60 days after the receipt of the FDA letter, to serve as nonvoting members to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting candidates. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting members to represent industry interests.

**IV. Application Procedure**

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see

**DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the 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 the mammography 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: October 26, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of General Medical Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Conference Grants.

*Date:* November 15, 2011.

*Time:* 12 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN18A, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* C. Craig Hyde, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical