

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM
Display Date 7-23-07
Publication Date 7-24-07
Certifier D. Hawkins

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Panels or Committees and Request for Nonvoting Industry Representatives on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) and certain device panels of the Medical Devices Advisory Committee 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 the FDA by [*insert date 30 days after date of publication in the **Federal Register***], for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by [*insert date 30 days after date of publication in the **Federal Register***].

N /

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 7520 Standish Pl. (MPN1), Rockville, MD 20855, 240-276-8938, e-mail: *kathleen.walker@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The agency intends to add nonvoting industry representatives to its advisory committee identified below:

I. CDRH—Various Committees and Panels

A. National Mammography Quality Assurance Advisory Committee (NMQAAC)

The Mammography Quality Standards Reauthorization Act of 2004 (Public Law 108-365) requires the addition of at least two industry representatives with expertise in mammography equipment to the NMQAAC.

B. Medical Devices Advisory Committee

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 one nonvoting member to represent the interests of the medical device manufacturing industry.

II. CDRH—Committee and Panel Functions

FDA is requesting nominations for nonvoting members representing industry interests for the following vacancies listed in table 1 of this document.

TABLE 1.

Committee Name or Panel	Approximate Date Needed
<p>NMQAAC—The functions of the NMQAAC are to advise FDA on the following topics: (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 that 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</p>	<p>February 1, 2008</p>
<p>Certain Panel of the Medical Devices Advisory Committee—The medical device panels perform the following functions: (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 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.</p> <p>Clinical Chemistry and Clinical Toxicology Devices Panel Gastroenterology and Urology Devices Panel Medical Devices Dispute Resolution Panel Microbiology Devices Panel Molecular and Clinical Genetics Devices Panel Orthopaedic and Rehabilitation Devices Panel Radiological Devices Panel</p>	<p>March 1, 2008 January 1, 2008 October 1, 2008 March 1, 2008 June 1, 2008 September 1, 2008 February 1, 2008</p>

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 contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. 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 committee or 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 of Food and Drugs will select the nonvoting member to represent industry interests.

IV. Qualifications

A. NMQAAC

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.

B. Medical Devices Advisory Committee

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.

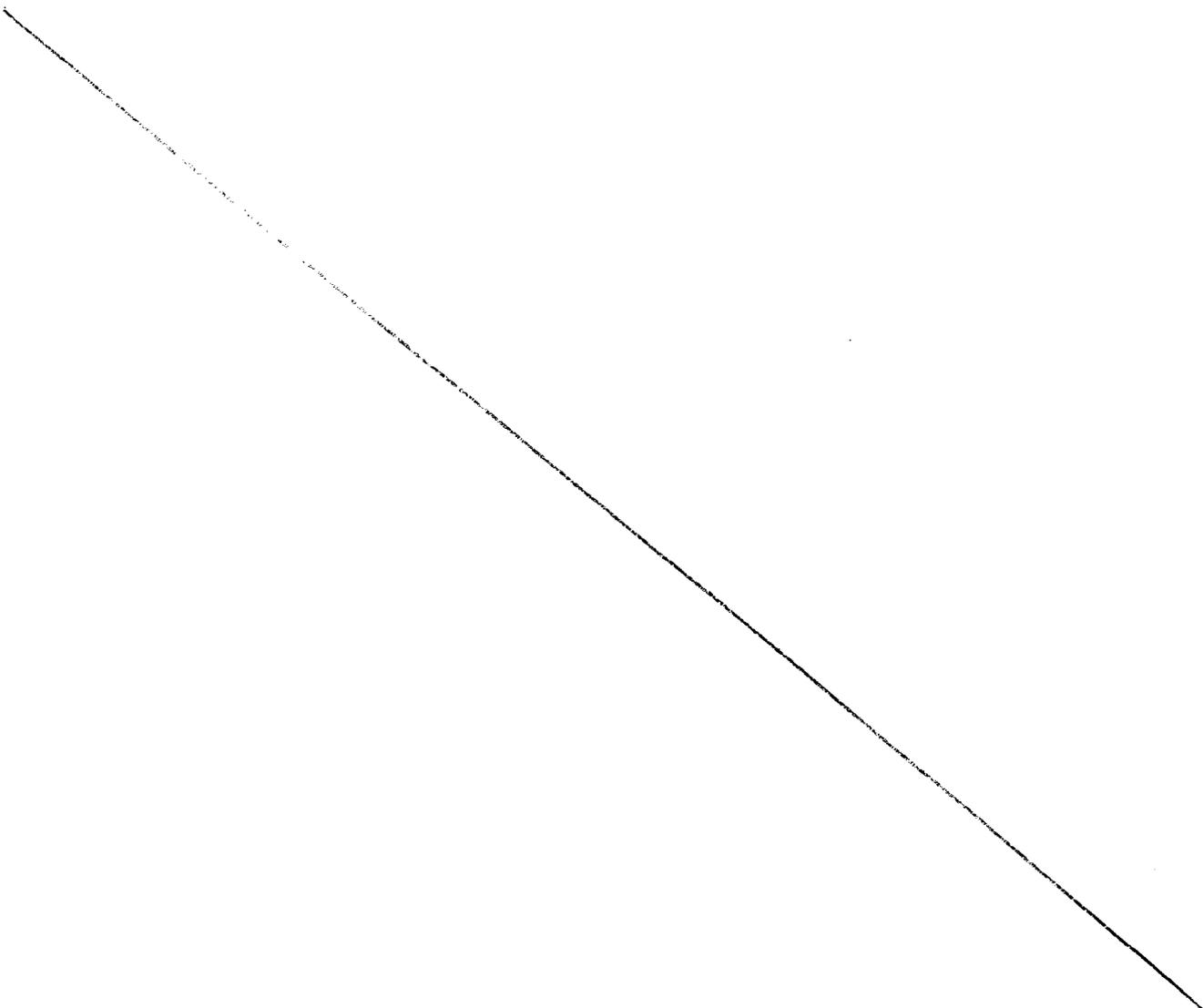
V. Application Procedure

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 (see **FOR FURTHER INFORMATION CONTACT**) within the 30 days. 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 food production and manufacturing industry; the dietary supplement manufacturing industry; and the agricultural biotechnology 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: 7/16/07
July 16, 2007.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Dawn P. Hawkins