4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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 Public Advisory Panels

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 Medical Devices Advisory Committee (MDAC) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in the CDRH. 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 organization 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].

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

FOR FURTHER INFORMATION CONTACT:

Margaret 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,

FAX: 301-847-8505,

e-mail: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Section 520(f)(3)of the Federal Food, Drug and Cosmetic Act (the FD&C 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. 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 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. Circulatory System Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory and vascular systems and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 make appropriate recommendations to the Commissioner of Food and Drugs.

C. Gastroenterology and Urology Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology and nephrology devices and makes appropriate recommendations to the Commissioner of Food and Drugs

D. General Hospital and Personal Use Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

E. Neurological Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the neurological system and makes appropriate recommendations to the Commissioner of Food and Drugs.

F. Obstetrics and Gynecology Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational obstetrics and gynecology devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

G. Ophthalmic Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of 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: December 3, 2012.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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