

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 3, 2014. On March 12, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 25, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Committee Management Staff, [james.clark@fda.hhs.gov](mailto:james.clark@fda.hhs.gov), or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 14, 2014.

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

[FR Doc. 2014-00939 Filed 1-17-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-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 the Device Good Manufacturing Practice Advisory Committee

**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 a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) 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 the upcoming vacancy effective with this notice.

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 device manufacturing industry.

**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 February 20, 2014, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by February 20, 2014.

**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:** Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)), as amended, provides that the DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative on the DGMPAC.

#### I. Function of DGMPAC

The DGMPAC reviews proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The DGMPAC also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

#### II. Qualifications

Persons nominated for the DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the DGMPAC's function.

#### 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. Attached to the letter will be 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 select a candidate to serve as the nonvoting member to represent industry interests for a particular committee within 60 days of receiving the FDA's

letter. 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. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. The nominee's 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).

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: January 14, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014-00964 Filed 1-17-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1633]

#### 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 upcoming 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 FDA (see **ADDRESSES**) by February 20, 2014, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by February 20, 2014.

**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. Telephone: 301-796-5960, Fax: 301-847-8505, email: [margaret.ames@fda.hhs.gov](mailto: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 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. Dental Products Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics, or bone physiology relative to the oral and maxillofacial area and makes appropriate recommendations to the Commissioner.

#### B. Hematology and Pathology 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 pathology, hematology, histopathology, cytotechnology, and molecular biology and makes appropriate recommendations to the Commissioner.

#### C. Immunology 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 oncology, immunology, and allergy 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 résumés. 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