

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Request for Nominations on the Technical Electronic Product Radiation Safety Standards Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting any industry organizations interested in participating in the selection of voting industry representatives to serve on the Technical Electronic Product Radiation Safety Standards Committee for the Center for Devices and Radiological Health to notify FDA in writing. FDA is also requesting nominations for voting industry representatives to serve on the Technical Electronic Product Radiation Safety Standards Committee. A nominee may either be self-nominated or nominated by an organization to serve as a voting 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 voting member to represent industry interests must send a letter stating that interest to FDA by *February 18, 2016*, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by February 18, 2016.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of voting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for voting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

#### 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, [margaret.ames@fda.hhs.gov](mailto:margaret.ames@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency requests nominations for voting industry representatives to the following advisory committee:

#### I. Technical Electronic Product Radiation Safety Standards Committee

This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products, to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

#### II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate voting 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 voting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the voting member to represent industry interests.

#### III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a voting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) 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 voting industry representatives will not participate in the selection process.

FDA seeks to include the views of women, 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.

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 11, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-00825 Filed 1-15-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Circulatory System Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 15 and 16, 2016, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel telephone number is 301-948-8900.

*Contact Person:* Dimitrus Culbreath, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3610, Silver Spring, MD 20993-0002, 301-796-6872, [Dimitrus.Culbreath@fda.hhs.gov](mailto:Dimitrus.Culbreath@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** On March 15, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System sponsored by Abbott Vascular. The Absorb GT1 BVS System is a temporary scaffold that will fully resorb over time and is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo native coronary artery lesions (length  $\leq$  24 millimeters (mm)) with a reference vessel diameter of  $\geq$  2.5 mm and  $\leq$  3.75 mm.

On March 16, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the AngelMed Guardian System sponsored by Angel Medical Systems, Inc. The AngelMed Guardian System is an implantable cardiac monitor intended to alert patients to ST segment shifts indicating coronary ischemia. The AngelMed Guardian System is intended for use in patients with prior acute coronary syndrome events, and at risk for recurrent events, to ST segment changes indicating cardiac ischemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background 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 1, 2016. Oral presentations from the public will be scheduled on March 15 and 16, 2016, 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 22, 2016. 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 24, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Artair Mallett at [artair.mallett@fda.hhs.gov](mailto:artair.mallett@fda.hhs.gov), 301-796-9638, 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 11, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-00824 Filed 1-15-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0073]

#### Request for Information on Psychosocial Predictors of Uptake of Tobacco and Other Products

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

**ACTION:** Notice; request for information.

**SUMMARY:** The Food and Drug Administration (FDA), Center for

Tobacco Products (CTP), is opening a docket to obtain data and information related to psychosocial predictors of uptake and continued use of tobacco products, including specific categories of tobacco products and specific individual tobacco products, as well as other products from which predictors may be adapted for or extrapolated to tobacco products. FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases. The purpose of this request for information (RFI) is to gather additional information that could help identify and evaluate predictors of consumer initiation, uptake, and use of tobacco products. FDA has already searched the publicly available scientific literature and is now seeking to supplement that with information that is not included in the published scientific literature.

**DATES:** Submit either electronic or written comments or information by March 4, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food