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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3224]

Request for Nominations for Voting Members for the Patient
Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting
nominations for members to serve on the Patient Engagement Advisory
Committee (the Committee), Office of the Center Director, Center for
Devices and Radiological Health.

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.

DATES: Nominations received by November 20, 2015, will be given first
consideration for membership on the Committee. Nominations received
after November 20, 2015, will be considered for nomination to the
Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically
by logging into the FDA Advisory Committee Membership Nomination
Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, 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, or by FAX: 301-847-8640.
Information about becoming a member on 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: Letise Williams, Center for Devices
and Radiological Health, Food and Drug Administration, 10903 New
Hampshire Ave., Bldg. 66, Rm. 5441, 301-796-8398, FAX: 301-847-8510,
Letise.Williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting
members for the Committee.

Elsewhere in this issue of the Federal Register, FDA is publishing
separate documents regarding:

1. Patient Engagement Advisory Committee; Notice of Establishment.
2. Request for Nominations of Individuals and Industry
Organizations for the Patient Engagement Advisory Committee.
3. Request for Nominations of Individuals and Consumer
Organizations for the Patient Engagement Advisory Committee.

I. General Description of the Committee's Duties

The Committee provides advice on complex issues relating to medical
devices, the regulation of devices, and their use by patients. Agency
guidance

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and policies, clinical trial or registry design, patient preference
study design, benefit-risk determinations, device labeling, unmet
clinical needs, available alternatives, patient reported outcomes and
device-related quality of life or health status issues are among the
topics that may be considered by the Committee. Members are
knowledgeable in areas such as clinical research, primary care patient
experience, healthcare needs of patient groups in the United States, or
are experienced in the work of patient and health professional
organizations, methodologies for eliciting patient preferences, and

strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs or designee from among authorities who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects. Members will be invited to serve for overlapping terms of up to 4 years. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area. Almost all non-Federal members of this Committee serve as Special Government Employees.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted. Nominations should include a cover letter; a current, complete resume or curriculum vitae for each nominee, including a current business and/or home address, telephone number, and email address if available; and should specify the advisory committee for which the nominee is recommended. Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

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: September 15, 2015.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

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