4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration's (FDA) is requesting additional nominations for members to serve on the Center for Devices and Radiological Health's (CDRH) Patient Engagement Advisory Committee (the PEAC or Committee). The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

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, particularly encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received by [45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], will be given first consideration for membership on the Committee. Nominations received after [45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], 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 please select Academician/Practitioner in the drop down menu, to apply for membership, 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, 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. 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.

I. General Description of the Committee's Duties

The PEAC provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes and increase integration of patient perspectives into the regulatory process for medical devices.

The PEAC provides advice on issues relating to medical devices, the regulation of devices, and their use by patients. A variety of topics may be considered by the PEAC, including Agency guidance 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.

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 candidates 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 participants. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area.

Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from Industry.

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 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner,

Special Medical Programs

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