4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of a pool of nonvoting industry representatives to serve as temporary nonvoting members on the Patient Engagement Advisory Committee (the Committee) in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for temporary nonvoting industry representatives to be included in a pool of individuals to serve on the Committee. Nominees recommended to serve as a temporary nonvoting industry representative may either be self-nominated or nominated by an industry organization. This position may be filled by representatives from different medical device areas based on expertise relevant to the topics being considered by the Committee. Nominations will be accepted for upcoming vacancies 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.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the

FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (see sections I and II of this document for details). 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 statements of interest from industry organizations interested in participating in the selection process of a pool of nonvoting industry representatives should be sent electronically to Margaret Ames (see FOR FURTHER INFORMATION CONTACT). All nominations for nonvoting industry representatives should 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 on an FDA advisory committee can also be obtained by visiting FDA's website at https://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. 5213, Silver Spring, MD 20993-0002, 301-796-5960, email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a pool of nonvoting industry representatives for the Committee. The list of needed expertise on May 1, 2020, is identified below:

(1) Cybersecurity

(2) Communication of Benefit and Risk Information to Patients; Medical Device Labeling

(3) Digital Health Technology/Artificial Intelligence

(4) Health of Women/Pediatrics (Vulnerable Population Groups)

(5) Patient Engagement

(6) Patient Preference Elicitation

(7) Patient-reported Outcomes Development, Validation, and Use in Regulatory Studies or Clinical Practice

(8) Postmarket Studies, including Observational and Registry-based Studies

FDA is publishing separate documents regarding:

1. Request for Nominations for Voting Members for the Patient Engagement Advisory Committee
2. Request for Nominations for Consumer Representative 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 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. The Commissioner of Food and Drugs (the Commissioner), or designee, shall have the

authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic(s).

II. Qualifications

Persons nominated for the Patient Engagement Advisory Committee should be full-time employees of firms that manufacture medical device products, 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 interest must 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 or curriculum vitae. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate or candidates (to serve in a pool of individuals with varying areas of expertise) to represent industry interest for the Committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate or candidates. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members (or pool of individuals) to represent industry interests.

IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include

a cover letter and a current, complete resume or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see ADDRESSES). Nominations should specify the advisory committee for which the nominee is recommended within 30 days of publication of this document (see DATES). In addition, nominations should acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the Committee. Only interested industry organizations participate in the selection process. 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: February 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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