Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 15, 2015.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–23571 Filed 9–18–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3224]

Request for Nominations of Individuals and Consumer 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 any consumer organizations interested in participating in the selection of a voting consumer representative to serve on the Patient Engagement Advisory Committee (the Committee) notify FDA in writing. FDA is also requesting nominations for a voting consumer representative to serve on the Committee. Nominees recommended to serve as a voting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for the current 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.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests on the Committee may send a letter or email stating that interest to FDA by October 21, 2015. Concurrently, nomination materials for prospective candidates should be sent electronically to Kimberly Hamilton (see FOR FURTHER INFORMATION CONTACT). All Consumer Representative nominations may be submitted electronically by accessing 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. 5117, Silver Spring, MD 20993–0002, or FAX: 301–847–8640. 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: For questions relating to participation in the nomination process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5117, Silver Spring, MD 20993–0002, 301–796–6319, kimberly.hamilton@fda.hhs.gov. For questions relating to the Committee: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, 301–796–8398, letise.williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a voting consumer representative on the Committee. Elsewhere in this issue of the Federal Register, FDA is publishing separate documents regarding:

1. Patient Engagement Advisory Committee; Notice of Establishment.

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, health care needs of patient groups in the