4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (PEAC). The general function of the committee is to provide advice and recommendations to the Agency on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public. This meeting will be the inaugural meeting of a new advisory committee.

DATES: The meeting will be held on October 11, 2017, from 1 p.m. to 5 p.m. and October 12, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy, Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.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, Silver Spring, MD 20993-0002, 301-796-8398, 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.

SUPPLEMENTARY INFORMATION:

Agenda: On October 11 and 12, 2017, the committee will discuss and make recommendations on the topic of patient input into medical device clinical trials. This meeting will provide the opportunity to bring patients, patient organization, FDA, industry, and other medical and scientific experts together for a broader discussion on this important patient-related issue.

This meeting is a key part of FDA's goal to help assure the needs and experiences of patients are included as part of FDA's deliberations involving the regulation of medical devices and their use by patients. For this meeting, FDA is seeking input from the PEAC and the public on topics such as to: (1) Better understand challenges for patients in medical device clinical trials, (2) better understand how patient input and engagement is being used to overcome these challenges (potential solutions), and (3) receive recommendations from the PEAC on top areas for FDA to consider for action.

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 September 20, 2017. Oral presentations from the public will be scheduled between approximately 3:40 p.m. to 4:10 p.m. on October 11, 2017, and approximately 9 a.m. to 9:30 a.m. and 2:30 p.m. to 3 p.m. on October 12, 2017. 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 September 12, 2017. 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 September 13, 2017.

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 AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 301-796-5966 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. Please be advised that, for the round table portion of the meeting, FDA will prepare a summary of discussion instead of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 20, 2017.

Anna K. Abram,

Deputy Commiissioner for Policy, Planning, Legislation, and Analysis.

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