



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2809]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (the Committee).

The general function of the Committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients.

The meeting will be open to the public.

DATES: The meeting will be held on September 10, 2019, from 8 a.m. to 5:30 p.m.

ADDRESSES: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900; additional information is available online at <https://www.ihg.com/holidayinn/hotels/us/en/gaithersburg/wasrv/hoteldetail>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

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, letise.williams@fda.hhs.gov, 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 website at <https://www.fda.gov/advisory-committees> 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 September 10, 2019, the Committee will discuss and make recommendations on the topic "Cybersecurity in Medical Devices: Communication That Empowers Patients." Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients. These same features may also increase cybersecurity risks. Preserving the benefit of these devices requires continuous vigilance as well as timely and effective communication to medical device users about evolving cybersecurity risks. The recommendations provided by the committee will address which factors should be considered by FDA and industry when communicating cybersecurity risks to patients and to the public, including but not limited to the content, phrasing, the methods used to disseminate the message and the timing of that communication. The recommendations will also address concerns patients have about changes to their devices to reduce cybersecurity risks as well as the role of other stakeholders such as healthcare providers in communicating cybersecurity risks to patients. Additional information about cybersecurity can be found at <https://www.fda.gov/medical-devices/digital-health/cybersecurity>.

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 website 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 website after the meeting. Background material is available at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2019 Meeting Materials.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 12:15 p.m. on September 10, 2019. 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 July 22, 2019. 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 July 24, 2019. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the Committee may send written submissions to the contact person on or before July 30, 2019.

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 Artair Mallett at Artair.Mallett@fda.hhs.gov, or 301-796-9638 at least 7 days in advance of the meeting.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings. Please be advised that, for the roundtable portion of the meeting, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

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

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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