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 May 17, 2017, the VRBPAC will meet in an open session to discuss considerations for evaluation of Respiratory Syncytial Virus vaccine candidates in seronegative infants. 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 May 10, 2017. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. 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 May 2, 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 May 3, 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 CAPT Serina Hunter-Thomas 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/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Science Board to the Food and Drug Administration 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 Science Board to the FDA. The general function of the committee is to provide advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency’s research agenda and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs. This meeting is open to the public.

DATES: The meeting will be held on May 9, 2017, from 2 p.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave, Bldg. 31, Rm. 1404, Silver Spring, MD 20993. This meeting will take place via audio Webcast. To access the link for the audio Webcast check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link. 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/ucm408555.htm.

For those unable to access the audio Webcast, a conference room with a speakerphone will be reserved at the meeting location provided at the top of the ADDRESSES section. Seating is limited and is available on a first come, first served basis.

FOR FURTHER INFORMATION CONTACT:
Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 1, Rm. 3309, Silver Spring MD 20993, 301–796–4769, rakesh.raghuwanshi@fda.hhs.gov, 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: The Science Board will provide recommendations on the Agency’s Innovation Funds work plan as prescribed in section 1002 of the 21st Century Cures Act (Pub. L. 114–255).

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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Reducing the Risk of Preventable Adverse Drug Events Associated With Hypoglycemia in the Older Population; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER), Professional Affairs and Stakeholder Engagement Staff (PASES), is announcing a 1-day public workshop entitled “Reducing the Risk of Preventable Adverse Drug Events Associated With Hypoglycemia in the Older Population.” The purpose of this workshop is to: (1) Discuss the importance of individualized glycemic control targets for older patients with diabetes, in order to reduce the risk of serious hypoglycemia; (2) identify and discuss medication safety efforts, both those that are part of the Safe Use Initiative and those external to FDA, that are of direct relevance and importance to older patients living with the disease; (3) discuss future areas of research which could be explored to reduce the risk of serious hypoglycemia in older diabetic patients; and (4) disseminate the results of this discussion to inform patients, patient advocates, and health care practitioners.

II. Topics for Discussion at the Public Workshop

The symposium will feature presentations on the scope of hypoglycemia-related adverse drug events in the older population, the risks and benefits of various degrees of glycemic control, factors affecting patient centered care, research into effective diabetes management, and the concept and translation of individualized glycemic targets to minimize adverse events in practice settings. Presenters will represent multidisciplinary backgrounds from government, academia, patient safety groups, health care industry, and clinicians. There will be opportunities for collaboration between speakers and attendees as well as question and answer sessions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm538666.htm?SSContributor=true. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 29, 2017, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit,