

[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).

Dated: April 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

[FR Doc. 2017-08189 Filed 4-21-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public symposium.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied.

DATES: The public symposium will be held on June 15, 2017, from 8 a.m. to 4 p.m.

ADDRESSES: The public symposium will be held at FDA's White Oak campus, 10903 New Hampshire Ave, Bldg. 31 (The Great Room C), Silver Spring, MD 20903. Entrance for the public symposium participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Christine Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-4228, email: CDERSafeUseInitiative@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting, such as the use of inappropriate medications in particular age groups, drug-drug interactions, unintended exposures, and misuse; and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied. This information may assist FDA in identifying significant and unexplored areas of preventable harm from drugs for the purpose of funding future research through the Safe Use Initiative. The symposium will feature presentations on sources of outpatient preventable harms, possible interventions, and future research topics. Areas to be discussed include identifying drugs and populations associated with a higher risk of preventable harm, as well as events which may be amenable to interventions. Methods to measure the effect of interventions and how to apply these to the outpatient setting will also be an important focus of discussion.

Presenters will represent multidisciplinary backgrounds from government, academia, patient safety groups, health care industry, and clinicians. There will be opportunities for interaction between speakers and attendees as well as question and answer sessions.

Registration: There is no registration fee to attend the public symposium. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this symposium must register online at <http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm538670.htm?SSContributor=true>. For those without Internet access, please contact Christine Lee (see **FOR FURTHER INFORMATION CONTACT**) to register. If you need special accommodations due to a disability, please contact Christine Lee at least 7 days in advance.

Transcripts: A transcript of the symposium will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the Internet at <https://www.regulations.gov> approximately 30 days after the

symposium. Transcripts will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <https://www.fda.gov>.

Dated: April 17, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Vaccines and Related Biological Products 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 Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on May 17, 2017, from 8:30 a.m. to 4:45 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be Web Cast and will be available at the following link: <https://collaboration.fda.gov/rsvvaccine0517>. 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: CAPT Serina Hunter-Thomas or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, at 240-402-5771 serina.hunter-thomas@fda.hhs.gov and 240-402-8072, rosanna.harvey@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: 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/AboutAdvisoryCommittees/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).

Dated: April 18, 2017.

Anna K. Abram,

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

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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/AboutAdvisoryCommittees/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 Raghuvanshi, 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.raghuvanshi@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