



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-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 or Agency) 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. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 4, 2020, from 8:30 a.m. to 5:10 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 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 webcast and will be available at the following link:

<https://collaboration.fda.gov/vrbpac030420/>. 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, 301-796-7864,

Kathleen.Hayes@fda.hhs.gov, or 301-796-4620, monique.hill@fda.hhs.gov, respectively; or the 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/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 March 4, 2020, under Topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2020 to 2021 influenza season. Also, on March 4, 2020, under Topic II, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Respiratory and Special Pathogens (LRSP), Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, CBER.

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/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 February 26, 2020. Oral presentations from the public will be scheduled between approximately 12:50 p.m. and 1:35 p.m. for the influenza strain selection portion of the meeting and 3:55 p.m. to 4:10 p.m. for the overview portion of the LRSP Site Visit. 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 February 18, 2020. 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 February 19, 2020.

Closed Committee Deliberations: On March 4, 2020, from 4:10 p.m. to 5:10 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

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 Kathleen Hayes (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at:

<https://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: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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