

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
187th Meeting of the Vaccines and Related Biological Products
Advisory Committee
October 10, 2024
AGENDA

Topic I: Discuss the Strain Selection for the Influenza Virus Vaccines for the 2025 Southern Hemisphere Influenza Season

EST Time	Presentation/Presenter
8:00 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (5 min)</u></p> <p>Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 min)</u></p> <p>Kathleen Hayes, MPH Designated Federal Officer, VRBPAC Division of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA</p>
8:20 a.m.	<p><u>Introduction to VRBPAC Meeting Topics (10 min total including Q&A)</u></p> <p>David C. Kaslow, M.D. (5 Min) Director, Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 Min</p>
8:30 a.m.	<p><u>Introduction to Seasonal Influenza Vaccine Strain Selection Southern Hemisphere 2025 (15 min total including Q&A)</u></p> <p>Jerry Weir, Ph.D. (10 min) Director, Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 Min</p>

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8:45 a.m.	<p><u>CDC: Global Seasonal Influenza Virus Surveillance and Characterization</u> (60 min total including Q&A)</p> <p>Rebecca G. Kondor, Ph.D. (45 min) Interim Director, WHO Collaborating Center for Surveillance Epidemiology and Control of Influenza Lead, Genomic Analysis Team Virology Surveillance and Diagnosis Branch (VSDB) Influenza Division, National Center for Immunizations and Respiratory Diseases (NCIRD), CDC</p> <p>Q&A: 15 min</p>
9:30 a.m.	Break (10 min)
9:40 a.m.	<u>OPH</u>
9:40 a.m.	<u>Committee Discussion, Recommendations, and Voting</u> (60 min)
10:20 a.m.	Topic I adjourned

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Topic II: Discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines

EST Time	Presentation/Presenter
10:20 a.m.	<p><u>Call to Order (5 min)</u></p> <p>Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine</p>
10:35 a.m.	<p><u>Introduction to Highly Pathogenic Avian Influenza (H5) Virus Vaccines (15 min total including Q&A)</u></p> <p>Jerry Weir, Ph.D. (10 min) Director, Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 min</p>
10:50 a.m.	<p><u>CDC: Highly Pathogenic Avian Influenza A(H5Nx) Virus Surveillance and Characterization in the United States and Globally and Recommendations for Candidate Vaccine Virus Development (40 min total including Q&A)</u></p> <p>Todd Davis, Ph.D., MSPH (30 min) Acting Chief, Virology, Surveillance, and Diagnosis Branch Virology Surveillance and Diagnosis Branch (VSDB) Influenza Division, National Center for Immunizations and Respiratory Diseases (NCIRD), CDC</p> <p>Q&A: 10 min</p>
11:30 a.m.	<p><u>BARDA's Pandemic Influenza Preparedness and Response Program (20 min total including Q&A)</u></p> <p>Christine Oshansky, Ph.D. (10 min) Director, Pandemic Vaccines and Adjuvant Program Influenza and Emerging Infectious Diseases Division (IEIDD) Biomedical Advanced Research and Development Authority (BARDA)</p>

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	Q&A: 5 min
11:50 a.m.	Lunch Break (30 min)
12:20 p.m.	<u>OPH</u>
12:20 p.m.	<u>Committee Discussion</u> (60 min)
1:30 p.m.	Topic II adjourned and Break (10 min)

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Topic III: Hear an Overview of Research Programs in the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) and the Laboratory of DNA Viruses (LDNAV) in the Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER).

Time	Presentation/Presenter
1:40 p.m.	<p><u>Roll call, Conflict of Interest Statement (5 min)</u></p> <p>Kathleen Hayes, MPH Designated Federal Officer, VRBPAC Division of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA</p>
1:45 p.m.	<p><u>Overview of CBER Research Programs (15 min total including min Q&A)</u></p> <p>Karen Elkins, Ph.D. (10 min) Associate Director for Science (ADS) CBER, FDA</p> <p>Q&A: 5 min</p>
2:00 p.m.	<p><u>Overview of OVRR & DVP Research (15 min total including Q&A)</u></p> <p>Tod Merkel, Ph.D. (10 min) Associate Director for Research, Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 min</p>
2:10 p.m.	<p><u>Overview of Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) (15 min total including 5 min Q&A)</u></p> <p>Zhiping Ye, Ph.D. (10 min) Chief/Principal Investigator, LPRVD Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 min</p>

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2:15 p.m.	<p><u>Overview of Laboratory of DNA Viruses (LDNAV) (15 min total including 5 min Q&A)</u></p> <p>Keith Peden, Ph.D. (10 min) Chief/Principal Investigator, LDNAV Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q&A: 5 min</p>
2:25 p.m.	<u>Break (15 min)</u>
2:40 p.m.	<u>Open Public Hearing (20 min)</u>
2:40 p.m.	Break and Transition into Closed Session (10 min)
2:45 p.m.	<u>Closed session for Committee Discussion, Recommendation and Vote (60 min)</u>
3:45 p.m.	Meeting Adjourned