

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**187<sup>th</sup> 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**

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

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

<b>8:45 a.m.</b>	<b><u>CDC: Global Seasonal Influenza Virus Surveillance and Characterization</u> (60 min total including Q&amp;A)</b>  <b>Rebecca G. Kondor, Ph.D. (45 min)</b> 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  <b>Q&amp;A: 15 min</b>
<b>9:45 a.m.</b>	<b>Break (10 min)</b>
<b>9:55 a.m.</b>	<b><u>OPH</u> (20 min)</b>
<b>10:15 a.m.</b>	<b><u>Committee Discussion, Recommendations, and Voting</u> (60 min)</b>
<b>11:15 a.m.</b>	<b>Topic I adjourned and Lunch (30 min)</b>

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

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

<b>EST Time</b>	<b>Presentation/Presenter</b>
<b>11:45 a.m.</b>	<p><b><u>Call to Order (5 min)</u></b></p> <p><b>Hana El Sahly, M.D.</b>            Chair, VRBPAC            Professor, Department of Molecular Virology and Microbiology            Baylor College of Medicine</p>
<b>11:50 a.m.</b>	<p><b><u>Introduction to Highly Pathogenic Avian Influenza (H5) Virus Vaccines (15 min total including Q&amp;A)</u></b></p> <p><b>Jerry Weir, Ph.D. (10 min)</b>            Director, Division of Viral Products            Office of Vaccines Research and Review (OVRR)            CBER, FDA</p> <p><b>Q&amp;A: 5 min</b></p>
<b>12:05 p.m.</b>	<p><b><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&amp;A)</u></b></p> <p><b>Todd Davis, Ph.D., MSPH (30 min)</b>            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><b>Q&amp;A: 10 min</b></p>
<b>12:45 p.m.</b>	<p><b><u>BARDA's Pandemic Influenza Preparedness and Response Program (15 min total including Q&amp;A)</u></b></p> <p><b>Christine Oshansky, Ph.D. (10 min)</b>            Director, Pandemic Vaccines and Adjuvant Program            Influenza and Emerging Infectious Diseases Division (IEIDD)            Biomedical Advanced Research and Development Authority (BARDA)</p>

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

	<b>Q&amp;A: 5 min</b>
<b>1:00 p.m.</b>	<b>Break (10 min)</b>
<b>1:10 p.m.</b>	<b><u>OPH</u> (20 min)</b>
<b>1:30 p.m.</b>	<b><u>Committee Discussion</u> (60 min)</b>
<b>2:30 p.m.</b>	<b>Topic II adjourned and Break (10 min)</b>

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

**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).**

<b>Time</b>	<b>Presentation/Presenter</b>
<b>2:40 p.m.</b>	<p><b><u>Roll call, Conflict of Interest Statement (5 min)</u></b></p> <p><b>Kathleen Hayes, MPH</b>            Designated Federal Officer, VRBPAC            Division of Scientific Advisors and Consultants            Center for Biologics Evaluation and Research (CBER), FDA</p>
<b>2:45 p.m.</b>	<p><b><u>Overview of CBER Research Programs (15 min total including min Q&amp;A)</u></b></p> <p><b>Karen Elkins, Ph.D. (10 min)</b>            Associate Director for Science (ADS)            CBER, FDA</p> <p><b>Q&amp;A: 5 min</b></p>
<b>3:00 p.m.</b>	<p><b><u>Overview of OVRR &amp; DVP Research (15 min total including Q&amp;A)</u></b></p> <p><b>Tod Merkel, Ph.D. (10 min)</b>            Associate Director for Research, Office of Vaccines Research and Review (OVRR)            CBER, FDA</p> <p><b>Q&amp;A: 5 min</b></p>
<b>3:15 p.m.</b>	<p><b><u>Overview of Laboratory of Pediatric &amp; Respiratory Viral Diseases (LPRVD) (15 min total including 5 min Q&amp;A)</u></b></p> <p><b>Zhiping Ye, Ph.D. (10 min)</b>            Chief/Principal Investigator, LPRVD            Division of Viral Products            Office of Vaccines Research and Review (OVRR)            CBER, FDA</p> <p><b>Q&amp;A: 5 min</b></p>

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

<b>3:30 p.m.</b>	<b><u>Overview of Laboratory of DNA Viruses (LDNAV) (15 min total including 5 min Q&amp;A)</u></b>  <b>Keith Peden, Ph.D. (10 min)</b> Chief/Principal Investigator, LDNAV Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA  <b>Q&amp;A: 5 min</b>
<b>3:45 p.m.</b>	<b><u>Break (15 min)</u></b>
<b>4:00 p.m.</b>	<b><u>Open Public Hearing (20 min)</u></b>
<b>4:20 p.m.</b>	<b>Break and Transition into Closed Session (10 min)</b>
<b>4:30 p.m.</b>	<b><u>Closed session for Committee Discussion, Recommendation and Vote (60 min)</u></b>
<b>5:30 p.m.</b>	<b>Meeting Adjourned</b>