

**Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
168th Meeting of the Vaccines and Related Biological Products
Advisory Committee
September 30, 2021
AGENDA**

Topic I: Presentation of the Laboratory of Bacterial Polysaccharides (LBP), Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER)

Topic II: Strain Selection for the Influenza Virus Vaccines for the 2022 Southern Hemisphere Influenza Season

Topic I

Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order (10 Min)</u></p> <ul style="list-style-type: none"> • Hana El Sahly, M.D. Chair, VRBPAC <p><u>Administrative Announcements, Roll Call, Conflict of Interest Statement (20 Min)</u></p> <ul style="list-style-type: none"> • Kathleen Hayes, M.P.H. Designated Federal Officer, VRBPAC CBER, FDA
9:00 a.m.	<p><u>Overview of Research/Site Visit Process, CBER (15 Min)</u></p> <ul style="list-style-type: none"> • Monica (Burts) Young, Ph.D. Senior Advisor to the Associate Director for Research CBER/FDA – 10 Min • Q&A – 5 Min
9:20 a.m.	<p><u>Overview of the Office of Vaccines Research and Review (OVR) & Overview of the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP)</u></p> <ul style="list-style-type: none"> • Jay Slater, M.D. Director Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) Office of Vaccines Research and Review CBER/FDA – 15 Min • Q&A – 10 Min

9:45 a.m.	<p><u>Overview of the Laboratory of Bacterial Polysaccharides</u></p> <ul style="list-style-type: none"> Willie Vann, Ph.D. Chief Laboratory of Bacterial Polysaccharides (LBP) Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) Office of Vaccines Research and Review CBER/FDA – 15 Min Q&A – 10 Min
10:05 a.m.	BREAK (10 min)
10:15 a.m.	Open Public Hearing (OPH) – 30 Min
10:45 a.m.	<p>Closed Session <u>Committee Discussion, Recommendations and Vote (60 Min)</u></p>
11:45 a.m.	LUNCH BREAK (30 min)
Topic II: Strain Selection for the Influenza Virus Vaccines for the 2022 Southern Hemisphere Influenza Season	
12:15 p.m	<p><u>Conflict of Interest Statement</u> (10 Min)</p> <ul style="list-style-type: none"> Kathleen Hayes, M.P.H. Designated Federal Officer, VRBPAC CBER, FDA
12:25 p.m.	<p><u>Introduction and Presentation of Questions</u></p> <ul style="list-style-type: none"> Anissa Cheung, M.Sc. Regulatory Coordinator Division of Viral Products Office of Vaccines Research and Review CBER/FDA – 15 Min Q&A – 5 Min
12:45 p.m.	<p><u>World Surveillance</u></p> <ul style="list-style-type: none"> David Wentworth, Ph.D. Chief Virology Surveillance and Diagnosis Branch Influenza Division National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention – 60 Min Q&A – 15 Min

2:00 p.m.	BREAK (10 min)
2:10 p.m.	Open Public Hearing (OPH) – 30 Min
2:40 p.m.	<u>Committee Discussion, Recommendations, and Vote</u> - 60 Min
3:40 p.m.	Adjourn Meeting