FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
159th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)
FDA White Oak Campus, Building 31, Great Room Salon B & C
Silver Spring, MD
March 4, 2020
AGENDA
Meeting Link:
https://collaboration.fda.gov/vrbpac030420/

March 4, 2020

Topic I: Strain Selection for the Influenza Virus Vaccines for the 2020 – 2021 Influenza Season
Topic II: Presentation of the Laboratory of Respiratory and Special Pathogens (LRSP), Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER)

Note: Committee members are participating in person

Time	Presentation/Presenter
8:30am – 8:40am	**Opening Remarks: Call to Order, Introduction of Committee** Hana El Sahly, M.D. Chair, VRBPAC
8:40am – 8:50am	**Administrative Announcements, Conflict of Interest Statement** Kathleen Hayes, M.P.H. Designated Federal Officer, VRBPAC CBER, FDA
8:50am – 9:00am	**Introduction** Anissa Cheung, M.Sc. Regulatory Coordinator Division of Viral Products Office of Vaccines Research and Review CBER/FDA
9:00am – 9:05am	Question & Answers
9:05am – 9:25am	**U.S. Surveillance** Lisa Grohskopf, M.D., M.P.H. CAPT USPHS Associate Chief for Policy & Liaison Activities, Epidemiology & Prevention Branch, Influenza Division Centers for Disease Control and Prevention (CDC)
9:25am – 9:30am	Question & Answers

9:30am – 10:30am	**<u>Global Influenza Virus Surveillance and Characterization</u>** David Wentworth, Ph.D. Branch Chief Influenza Division Virology, Surveillance, and Diagnostic Branch Centers for Disease Control and Prevention (CDC)
10:30am – 10:40am	Question & Answers
10:40am – 10:50am	**BREAK**
10:50am – 11:10am	**<u>DoD Vaccine Effectiveness Report</u>** Mark Scheckelhoff, Ph.D., M.P.H. CDR, USPHS Armed Forces Health Surveillance Branch
11:10am – 11:15am	Question & Answers
11:15am – 11:35am	**<u>Candidate Vaccine Strains & Potency Reagents</u>** Manju Joshi, Ph.D. Lead Biologist Division of Biological Standards & Quality Office of Compliance and Biologics Quality CBER/FDA
11:35am – 11:40am	Question & Answers
11:40am – 12:00pm	**<u>Comments from Manufacturer Representative</u>** Penny L. Post, Ph.D. Head of Regulatory Affairs Sanofi Pasteur
12:00pm – 12:05pm	Question & Answers
12:05pm – 12:50pm	**Lunch** (45 min.)
12:50pm – 1:35pm	**Open Public Hearing** (45 min.)
1:35pm – 2:45pm	**<u>Committee Discussion, Recommendations, and Vote</u>**
2:45pm	**Topic II: Laboratory of Respiratory and Special Pathogens (LRSP)** **Division of Bacterial, Parasitic, and Allergenic Products (DBPAP)** **Office of Vaccines Research and Review (OVRR)** **Center for Biologics Evaluation and Research (CBER)**

2:45pm – 2:50pm	**<u>Conflict of Interest Statement</u>** Kathleen Hayes, M.P.H. Designated Federal Officer, VRBPAC CBER, FDA
2:50pm – 3:05pm	**<u>Overview of Research/Site Visit Process, CBER</u>** Carolyn Wilson, Ph.D. Associate Director for Research CBER/FDA
3:05pm – 3:10pm	Question & Answers
3:10pm – 3:25pm	**<u>Overview of the Office of Vaccines Research and Review (OVRR) & Overview of the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP)</u>** Jay Slater, Ph.D. Director Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) Office of Vaccines Research and Review CBER/FDA
3:25pm - 3:30pm	Question & Answers
3:30pm – 3:40pm	**<u>Overview of the Laboratory of Respiratory and Special Pathogens</u>** Michael Schmitt, Ph.D. Chief Laboratory of Respiratory and Special Pathogens Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) Office of Vaccines Research and Review CBER/FDA
3:40pm – 3:45pm	Question & Answers
3:45pm – 3:55pm	**BREAK**
3:55pm – 4:10pm	**Open Public Hearing**
4:10pm – 5:10pm	**Closed Session** **<u>Committee Discussion, Recommendations and Vote</u>**
5:10pm	**Adjourn Meeting**