

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)**

Thursday, March 1, 2018

**151st Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)
FDA White Oak Campus – Great Room
Silver Spring, MD 20993**

Live Webcast: <https://collaboration.fda.gov/vrbpac030118>

AGENDA

Time	Presentation/ Presenter
8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee Kathryn Edwards, M.D. Chair, VRBPAC Conflict of Interest Statement Serina Hunter-Thomas Designated Federal Officer VRBPAC, FDA

Topic I: Presentation of Laboratory of Mucosal Pathogens & Cellular Immunology (LMPCI), Division of Bacterial, Parasitic & Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER)

8:15 a.m.	Overview of Research/Site Visit Process, CBER Carolyn Wilson, Ph.D. Associate Director for Research CBER/FDA
8:30 a.m.	Overview of DBPAP Jay Slater, M.D. Director, DBPAP OVR/CBER/FDA
8:45 a.m.	Overview of LMPCI Scott Stibitz, Ph.D. Chief, LMPCI DBPAP/OVR/CBER/FDA

9:00 a.m.	Open Public Hearing
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9:15 a.m. **Closed Session**

9:45 a.m. Break

Topic II: Strain Selection for the Influenza Virus Vaccines for the 2018-2019 Influenza Season

10:15 a.m. **Conflict of Interest Statement**

Serina Hunter-Thomas
Designated Federal Officer
VRBPAC, FDA

Time Presentation/ Presenter

10:25 a.m. **Introduction**

Anissa Cheung, M.Sc.
Regulatory Coordinator
Division of Viral Products
Office of Vaccines Research and Review
CBER/FDA

10:35 a.m. **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

Time	Presentation/ Presenter
11:00 a.m.	<p>World Surveillance/Virus Characterization</p> <p>Jacqueline Katz, Ph.D. Deputy Director, Influenza Division and Director, WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention</p>
12:05 p.m	<p>DoD Vaccine Effectiveness Report</p> <p>Angelia Cost, Ph.D., Sc.M. Senior Managing Epidemiologist Armed Forces Health Surveillance Branch Public Health Division Defense Health Agency</p>
12:30 p.m.	<p>Lunch</p>
1:30 p.m.	<p>Candidate Vaccine Strains& Potency Reagents</p> <p>Manju Joshi, Ph.D. Lead Biologist Division of Biological Standards & Quality Office of Compliance and Biologics Quality CBER/FDA</p>
1:50 p.m.	<p>Comments from Manufacturers</p> <p>Penny Post, Ph.D. Head of Regulatory Affairs, Flublok Protein Sciences Corporation a Sanofi Company</p>
2:10 p.m.	<p>Open Public Hearing</p>
2:55 p.m.	<p>Committee Discussion, Voting, and Recommendations</p>
4:00 p.m.	<p>Adjournment</p>