FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
190th Meeting of the Vaccines and Related Biological Products Advisory Committee
October 9, 2025
AGENDA

Topic I: To discuss and make recommendations on the selection of strains for influenza virus vaccines for the 2025 Southern Hemisphere influenza season-

EST Time	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 min)** **Hana El Sahly, MD** Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 min)** **LCDR Cicely C. Reese, PharmD** Designated Federal Officer, VRBPAC Center for Biologics Evaluation and Research (CBER), FDA
8:50 a.m.	**Open Public Hearing (up to 30 mins)**
8:55 a.m.	**Introduction to VRBPAC Meeting Topics (10 min total including Q&A)** **David C. Kaslow, MD (5 Min)** Director, Office of Vaccines Research and Review (OVRR) CBER, FDA **Q&A: 5 Min**
9:05 a.m.	**Introduction to Seasonal Influenza Vaccine Strain Selection Southern Hemisphere 2025 (15 min total including Q&A)** **Jerry Weir, PhD (10 min)** Director, Division of Viral Products Office of Vaccines Research and Review (OVRR) CBER, FDA **Q&A: 5 Min**

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9:20 a.m.	**<u>CDC: Global Seasonal Influenza Virus Surveillance and Characterization</u> (60 min total including Q&A)** **Rebecca G. Kondor, PhD (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 **Q&A: 15 min**
10:20 a.m.	**Break (10 min)**
10:30 a.m.	**<u>Committee Discussion, Recommendations, and Voting</u> (60 min)**
11:30 a.m.	**Topic I Adjourned and Lunch (30 min)**

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Topic II: To discuss and make recommendations on advancing CBER's allergen standardization program.

EST Time	Presentation/Presenter
12:00 p.m.	**Call to Order (5 min)** **Hana El Sahly, MD** Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Roll Call, Conflict of Interest statement** **LCDR Cicely C. Reese, PharmD** Designated Federal Officer, VRBPAC Center for Biologics Evaluation and Research (CBER), FDA
12:05 p.m.	**OPH (up to 30 min)**
12:10 p.m.	**Replacement of Radial Immunodiffusion (RID) Assays of Currently Standardized Extracts with ELISA or Aptamer-based Enzymatic Assays (45 min total including Q&A)** **Ronald L. Rabin, MD (35 min)** Chief, Laboratory of Immunobiochemistry (LIB) Division of Bacterial, Parasitic and Allergenic Products (DBPAP) Office of Vaccines Research and Review (OVRR) CBER, FDA **Q&A: 10 min**
12:55 p.m.	**Use of Tandem LC/MS/MS to Measure Potencies of Complex Extracts with Multiple "Major Allergens,"** **Use of HDM Bodies and Fecal Pellets as Source Materials for HDM Extracts (50 min total including Q&A)**

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	Ronald L. Rabin, MD **Michael Brad Strader, PhD (40 min)** Laboratory of Immunobiochemistry (LIB) Division of Bacterial, Parasitic and Allergenic Products (DBPAP) Office of Vaccines Research and Review (OVRR) CBER, FDA **Q&A: 10 min**
1:45 p.m.	**<u>Approaches to Allergen Standardization Related to Dust Mites</u>** **(40 min total including Q&A)** **Thomas Platts-Mills, MD (30 min)** Professor of Medicine Division of Asthma, Allergy, and Immunology Department of Medicine University of Virginia School of Medicine, Charlottesville, VA **Q&A: 10 min**
2:25 p.m.	**<u>Industry Perspective from the Allergen Products Manufacturers' Association (APMA)</u> (30 min total including Q&A)** **Trenna Repp (20 min)** **President, APMA** **Q&A: 10 min**
2:55 p.m.	**Break (10 min)**
3:05 p.m.	**<u>Committee Discussion, Recommendations, and Voting</u> (120 min)**
5:05 p.m.	**Topic II Adjourned, Meeting Adjourned**