U.S. FOOD & DRUG ADMINISTRATION

Introduction

190th Vaccines and Related Biological Products Advisory Committee Meeting

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190th VRBPAC Meeting Topics

Topic I: To discuss and make recommendations on the selection of strains for influenza virus vaccines for the 2026 Southern Hemisphere influenza season.

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

Topic I: To discuss and make recommendations on the selection of strains for influenza virus vaccines for the 2026 Southern Hemisphere influenza season.

- Introduction to Seasonal Influenza Vaccine Strain Selection Southern Hemisphere 2026
  - Dr. Jerry Weir, FDA
- CDC: Global Seasonal Influenza Virus Surveillance and Characterization
  - Dr. Rebecca Kondor, CDC
- Committee Discussion, Recommendations, and Voting

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

Voting Question

1. For the composition of egg-based trivalent 2026 SH formulations of influenza vaccines, does the committee recommend:
   - An A/Missouri/11/2025 (H1N1)pdm09-like virus;
   - An A/Singapore/GP20238/2024 (H3N2)-like virus; and
   - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

190th VRBPAC Meeting Topics

Topic I: To discuss and make recommendations on the selection of strains for influenza virus vaccines for the 2026 Southern Hemisphere influenza season.

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

Proposed Modernization Strategy

Proposed Initiative 1: Updating Major Allergen Potency Standardization

Proposed Initiative 2: Expanding Standardization Program to Include Food Allergens and Additional Environmental Allergens

Proposed Initiative 3: Complex Extract Characterization by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)

Proposed Initiative 4: Optimization of House Dust Mite Extract Source Materials

APAC → VRBPAC

- Allergenic Products Advisory Committee (APAC)
  - Established 09 July 1984
  - Last convened (31st Meeting) 28 October 2021
  - Terminated 09 July 2024
- Incorporated into Vaccines and Related Biological Products Advisory Committee (VRBPAC) Charter
  - Temporary voting members (TVMs) (Topic II)
    - Dr. Amal Assa'ad
    - Dr. Carla Davis
    - Dr. Mark S. Dykewicz
    - Dr. Paul Greenberger

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

- Call to Order
  - Dr. Hana El Sahly
- Replacement of Radial Immunodiffusion (RID) Assays of Currently Standardized Extracts with ELISA or Aptamer-based Enzymatic Assays
  - Dr. Ronald L. Rabin
- 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
  - Drs. Ronald L. Rabin and Michael Brad Strader
- Approaches to Allergen Standardization Related to Dust Mites
  - Dr. Thomas Platts-Mills
- Industry Perspective from the Allergen Products Manufacturers' Association (APMA)
  - Trenna Repp
- Committee Discussion, Recommendations, and Voting

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

Voting Questions

Question 1: Mass Concentration Measurements
Does measurement of mass concentrations by ELISA of their major allergens provide a scientifically sound approach for expressing and reporting potencies of cat hair and pelt allergen extracts, and of short ragweed pollen allergen extracts?

Question 2: CBER's Allergenic Standardization Program
Are the revised assays for cat hair/pelt and ragweed pollen allergen extracts scientifically appropriate templates for expanding CBER's allergenic standardization program to include major food allergens and environmental allergens?

Question 3: LC/MS/MS Analytics
Does LC/MS/MS technology, compared with the currently used analytic technology, provide sufficient fit-for-purpose analytical capability for better characterization of complex allergen extracts to improve product quality?

Question 4: House Dust Mite (HDM) Source Material
Do the available data support inclusion of both house dust mite (HDM) bodies and fecal pellets as source materials for HDM allergen extracts to more adequately mimic clinically relevant allergen exposure?


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