Summary

Meeting Title:

Interagency Meeting to discuss and make recommendations on the strain composition of influenza virus vaccines for use in United States during the 2025-2026 influenza season

Date &Time:

Thursday, March 13, 2025; 09:00am – 11:30am EST

Attendees:

Center for Biologics Evaluation and Research (CBER): Sudhakar Agnihothram, Karin Bok, Robert Daniels, Maryna Eichelberger, Manju Joshi, David C. Kaslow (Meeting Chair), Peter Marks, Julie Tierney, Jerry Weir, and Zhiping Ye

Centers for Disease Control and Prevention (CDC): Vivien Dugan, Lisa Grohskopf, and Rebecca Kondor

Department of Defense (DoD): Anthony Fries

Discussion Summary:

On March 13, 2025, at 8:57 a.m. Eastern Standard Time (EST), the interagency meeting convened in a closed session to discuss and make recommendations on the strain composition of influenza virus vaccines for use in United States during the 2025-2026 influenza season.

Dr. David C. Kaslow, Director of Office of Vaccines Research and Review (OVRR) and the meeting chair, called the meeting to order and made opening remarks. The meeting began with a 5-minute FDA Introduction by Dr. Jerry Weir, Director, Division of Viral Products, OVRR, CBER.

The Chair called upon CDC for two presentations. Dr. Lisa Grohskopf from CDC gave a 10-minute presentation on “U.S. Surveillance,” which was followed by a 35-minute presentation on “Global Influenza Virus Surveillance and Characterization” by Dr. Rebecca Kondor from CDC. A 6-minute Q&A session followed the two CDC presentations.

The Chair called upon DoD for a presentation. Dr. Anthony Fries from DoD gave a 15-minute presentation on “DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness,” which was followed by a 2-minute Q&A session.

The Chair called upon CBER for a presentation. Dr. Manju Joshi from CBER gave a 5-minute presentation on “Candidate Vaccine Strains and Potency Reagents.”

The Chair commenced the Discussion Session at 10:23 AM EST on the following two topics:

1. Recommendation of a trivalent 2025-2026 formulation for egg-based influenza virus vaccines in the U.S. that contains the following virus strains:

    - An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
    - An A/Croatia/10136RV/2023 (H3N2)-like virus; and
    - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

2. Recommendation of a trivalent 2025-2026 formulation for cell- and recombinant-based influenza vaccines in the U.S. that contains the following virus strains:
    - An A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
    - An A/District of Columbia/27/2023 (H3N2)-like virus; and
    - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

There was a general agreement among the participants that the data presented was informative and convincing of the need to change the recommended influenza A/H3N2 virus strains from the 2024-2025 Formula and to maintain the currently recommended influenza A/H1N1 and influenza B virus strains from the 2024-2025 Formula.

To adjourn the meeting at 10:35 AM EST, the Chair called upon Dr. Peter Marks, Director CBER, who thanked the interagency participants for delivering pertinent presentations and discussing the recommendations on the strain composition of influenza virus vaccines for use in United States during the 2025-2026 influenza season.