

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

Influenza Virus Vaccine Strain Selection 2024 - 2025 Northern Hemisphere

**Vaccines and Related Biological Products
Advisory Committee (03/05/2024)**

*Jerry P Weir, PhD, Director
Division of Viral Products/OVRR/CBER/FDA*

Purpose of Today's VRBPAC Committee Discussion



- Review influenza surveillance and epidemiology data, genetic and antigenic characteristics of recent virus isolates, serological responses to current vaccines, and the availability of candidate vaccine strains and reagents
- Make recommendations for the strains of influenza A (H1N1 and H3N2) and influenza B viruses to be included in the 2024-2025 Northern Hemisphere formulation of influenza vaccines licensed for use in the United States

Agenda Outline

- Introduction
- U.S. Influenza Virus Surveillance
- Global Influenza Virus Surveillance and Characterization
- DoD Influenza Virus Surveillance and Mid-Season Vaccine Effectiveness
- Candidate Vaccine Strains & Potency Reagents
- Comments from Manufacturers' Representative
- Committee Discussion and Voting

Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2023-2024



- WHO recommendation – February 24, 2023
- VRBPAC recommendation for the antigenic composition of the 2023-2024 influenza virus vaccines in the U.S. (March 7, 2023)
 - Influenza A (H1N1)
 - an A/Victoria/4897/2022 (H1N1)pdm09-like virus (Egg-based Vaccines)
 - an A/Wisconsin/67/2022 (H1N1)pdm09-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza A (H3N2)
 - an A/Darwin/9/2021 (H3N2)-like virus (Egg-based Vaccines)
 - an A/Darwin/6/2021 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza B (for trivalent and quadrivalent vaccines)
 - a B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - Influenza B (for quadrivalent vaccines containing the above 3 virus strains)
 - a B/Phuket/3073/2013-like virus (Yamagata lineage)

Most Recent Recommendations for Southern Hemisphere Influenza Vaccines - 2024

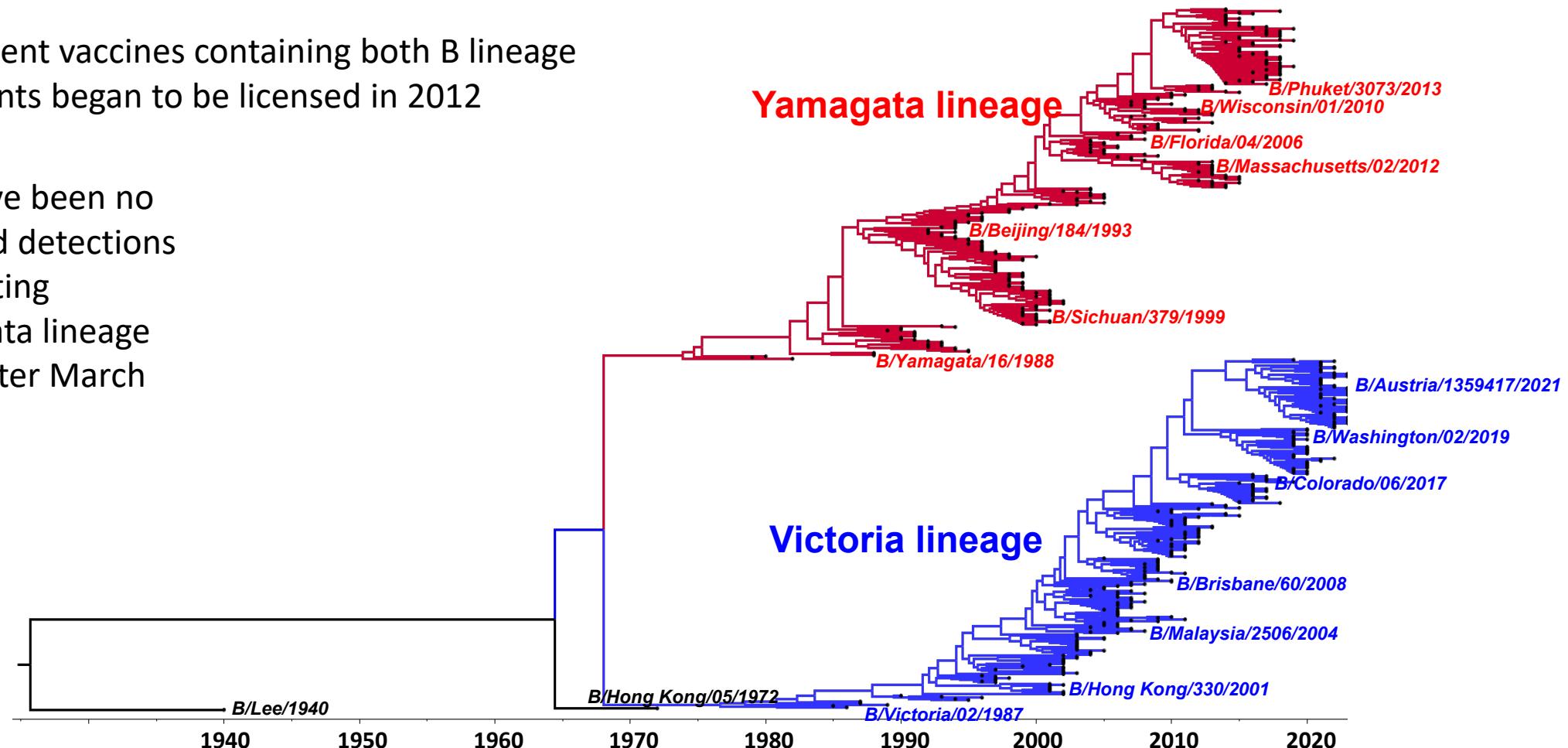


- WHO recommendation – September 29, 2023
- VRBPAC recommendation for virus strains to be included in the 2024 Southern Hemisphere formulation of influenza vaccine licensed in the United States (October 5, 2023)
 - The committee recommended that trivalent egg-based vaccines for use in the southern hemisphere influenza season contain:
 - An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
 - An A/Thailand/8/2022 (H3N2)-like virus; and
 - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus
 - For quadrivalent 2024 SH formulation of influenza vaccines, the committee recommended inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine
- At the VRBPAC meeting on October 5, 2023, the committee voted unanimously to “recommend excluding the B/Yamagata lineage antigen component from quadrivalent influenza vaccines as soon as possible”
 - Committee members emphasized the importance of setting firm timelines for implementing the exclusion of B/Yamagata lineage antigen from quadrivalent influenza vaccines and working toward a 2024–2025 implementation date for the U.S. vaccine in the Northern Hemisphere

B/Yamagata Virus Emergence and Possible Disappearance



- Influenza B diverged into 2 antigenically distinct lineages in the early 1980's; Yamagata viruses emerged from a B/Victoria like ancestral strain
- Quadrivalent vaccines containing both B lineage components began to be licensed in 2012
- There have been no confirmed detections of circulating B/Yamagata lineage viruses after March 2020



Removal of the B/Yamagata Component from the Vaccine – Update



- As noted at the VRBPAC meeting on 5 October 2023, there are regulatory and manufacturing challenges to reverting from a quadrivalent vaccine (H1, H3, B/Vic and B/Yam) to a trivalent with H1, H3 and B/Vic
 - These challenges differ in different parts of the world and a global coordinated change in vaccine composition to a trivalent formulation proved to be difficult
- Since the challenges to a trivalent formulation transition in the U.S. appeared manageable for 2024-2025, FDA engaged with all U.S. influenza vaccine manufacturers, together and separately, to identify necessary steps for trivalent formulation transition for the next NH influenza season
 - Each U.S. influenza vaccine manufacturer submitted updated regulatory files related to their TIV vaccines
 - Approval of all necessary regulatory submissions is on-track for 2024-2025 TIV implementation for all licensed U.S. influenza vaccine manufacturers
- Because QIV will still be distributed in other parts of the world, some U.S. influenza vaccine manufacturers will continue manufacturing both TIV and QIV for 2024-2025
 - Both TIV and QIV will be licensed for such manufacturers, but only TIV will be distributed in the U.S.
- The WHO recommended strains for the NH 2024-2025 influenza season on February 23, 2024, and reiterated earlier recommendations concerning the exclusion of a B/Yamagata strain component

WHO Recommendations for 2024-2025 Northern Hemisphere Influenza Vaccine



- WHO recommendation – February 23, 2024
- For trivalent vaccines for use in the 2024-2025 northern hemisphere influenza season, WHO recommends the following:
 - Egg-based vaccines
 - an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
 - an A/Thailand/8/2022 (H3N2)-like virus; and
 - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus
 - Cell culture- or recombinant-based vaccines
 - an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
 - an A/Massachusetts/18/2022 (H3N2)-like virus; and
 - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus
- The WHO again noted that there have been no confirmed cases of B/Yamagata-lineage viruses after March 2020 and reaffirmed their previous opinion that “the B/Yamagata lineage antigen should be excluded from influenza vaccines as it is no longer warranted”. However, “where quadrivalent vaccines are still used, the B/Yamagata lineage component remains unchanged from previous recommendations:”
 - a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

Voting Questions for the Committee

1. Does the committee recommend a trivalent 2024-2025 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/Thailand/8/2022 (H3N2)-like virus; and
 - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus
2. Does the committee recommend a trivalent 2024-2025 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/Massachusetts/18/2022 (H3N2)-like virus; and
 - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus
3. For U.S. licensed quadrivalent influenza vaccines intended for ex-U.S. distribution, does the committee recommend inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine



**U.S. FOOD & DRUG
ADMINISTRATION**