

January 2024

The Food and Drug Administration (FDA), in collaboration with the World Health Organization (WHO), has directed influenza vaccine manufacturers to remove the B/Yamagata influenza virus strain from all influenza vaccines, as soon as possible, preferably by the 2024-2025 influenza season.

Dear Valued Customer,

As your partner in public health, CSL Seqirus is sending this communication to inform you of an upcoming change for the 2024-2025 influenza season.

The Food and Drug Administration (FDA), in collaboration with the World Health Organization (WHO), has directed influenza vaccine manufacturers to remove the B/Yamagata influenza virus strain from all influenza vaccines, as soon as possible preferably by the 2024-2025 influenza season.

The FDA is confident in this decision because the WHO's dedicated, comprehensive, and reliable surveillance system for tracking influenza virus circulation has shown that B/Yamagata circulation was in decline prior to the COVID-19 pandemic and has subsequently confirmed zero circulating B/Yamagata lineage viruses since March of 2020.^{1,2}

It is extremely rare that a virus disappears from circulation, which is why the disappearance of B/Yamagata is a **public health success story** and one that is a testament to the importance of widely implemented influenza immunization programs, amongst other contributing factors such as the inherent characteristics and epidemiology of the B/Yamagata virus and the unique environment created by the COVID-19 pandemic.³

Given the removal of a strain (B/Yamagata) that no longer circulates from the influenza vaccine, transitioning from a quadrivalent to a trivalent ("TIV") formulation of influenza vaccines will NOT impact vaccine effectiveness.⁴ The composition of the new TIV formulations will be designed to match projected circulating strains based on the WHO's ongoing surveillance.

As a leader in influenza protection, CSL Seqirus is fully prepared for this change and will be bringing our full portfolio of influenza vaccines to the US market in trivalent formulations for the 2024-2025 influenza season.

CSL Seqirus moved with urgency to make this requested change happen because we are fully aligned with the FDA's position that this is the right decision for public health and that no vaccine should include a component that does not offer a benefit of improved effectiveness, safety, stability, and/or purity.

Additionally, by implementing this change quickly, and proactively and transparently sharing the information with healthcare providers and the public, we believe it will help **engender public health confidence in vaccines**, as we cannot afford any further erosion in vaccine confidence and immunization rates that could result in unnecessary morbidity and mortality.

From a pre-book process standpoint, there is **no difference in what you need to do**. Simply contact your CSL Seqirus Representative, the Customer Service Team (customerservice.us@seqirus.com), or visit flu360.com to secure your trivalent influenza vaccine supply for the upcoming 2024-2025 season to ensure as a healthcare community we are building back immunization rates, which have declined the past few seasons. In the coming months, we will provide office and patient educational materials to help message around this transition, as well as updated product NDC codes and updated CPT codes to ensure your staff can bill and code correctly for the trivalent influenza vaccines.

As always, CSL Seqirus is committed to supporting your immunization campaign goals through reliable supply, timely and transparent communications, and educational tools and resources.

Thank you for your continued work on the front line of public health.

Kind regards,

DAVE ROSS

VP COMMERCIAL OPERATIONS, NORTH AMERICA

Refs: 1.<u>Global Influenza Surveillance and Response System (GISRS) (who.int)</u> 2. <u>World Health Organization - FluNet</u> 3. <u>Nature Reviews - Influenza Lineage Extinction During The COVID-19 Pandemic</u> 4. <u>Information for the 2023-2024 Flu Season | CDC</u>