



September 13, 2023

COVID-19 Vaccine FDA Update and Removal of Deauthorized Vaccine

On September 11, 2023, the [U.S. Food and Drug Administration](#) approved and authorized emergency use of updated COVID-19 vaccines. These actions relate to updated mRNA vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc. Consistent with the [totality of the evidence](#) and input from the FDA's expert advisors, these vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.

The updated mRNA vaccines are each approved for individuals 12 years of age and older and are authorized under emergency use for individuals 6 months through 11 years of age. **As part of this action, the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.**

Medical waste disposal requirements are set by state or local environmental agencies and may vary by jurisdiction. **Please remove the current mRNA vaccines from your physical inventory immediately and dispose in compliance with vaccine disposal regulations.**

The U.S. Centers for Disease Control and Prevention's **Advisory Committee on Immunization Practices met yesterday (September 12)**, to discuss clinical recommendations on who should receive an updated vaccine, as well as further considerations for specific populations such as immunocompromised and older individuals. A separate SIREN will be sent with further details.

Related Information

- [Comirnaty](#) (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- [Spikevax](#) (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- [Moderna COVID-19 Vaccine](#) (2023-2024 Formula)
- [Pfizer-BioNTech COVID-19 Vaccine](#) (2023-2024 Formula)
- [FDA Resources for the Fall Respiratory Illness Season](#)
- [Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2023](#)
- [June 15, 2023, Meeting of the Vaccines and Related Biological Products Advisory Committee](#)