

Comirnaty[®] and Spikevax[®] (Omicron XBB.1.5) vaccines – FDA approval and Emergency Use Authorization

- On September 11, 2023, the [FDA approved Pfizer/BioNTech's Comirnaty \(Omicron XBB.1.5\)](#) and [Moderna's Spikevax \(Omicron XBB.1.5\) COVID-19 vaccines](#) in individuals 12 years of age and older as a single dose at least 2 months since the last dose of any COVID-19 vaccine.
- In addition, the FDA granted emergency use authorization (EUA) to [Pfizer/BioNTech's COVID-19 vaccine \(2023-2024 formula\)](#) and [Moderna's COVID-19 vaccine \(2023-2024 formula\)](#) in individuals from 6 months to 11 years of age.
 - Individuals 5 years to 11 years of age regardless of previous vaccination are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months since the last dose of any COVID-19 vaccine.
 - Individuals 6 months through 4 years of age who have previously been **vaccinated** against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
 - **Unvaccinated** individuals 6 months through 4 years of age are eligible to receive three doses of the updated authorized Pfizer/BioNTech COVID-19 vaccine or two doses of the updated authorized Moderna COVID-19 vaccine.
- As part of today's actions, the bivalent Moderna and Pfizer/BioNTech COVID-19 vaccines are no longer authorized for use in the U.S.
- The updated vaccines are expected to provide good protection against COVID-19 from the currently circulating variants. Barring the emergence of a markedly more virulent variant, the FDA anticipates that the composition of COVID-19 vaccines may need to be updated annually, as is done for the seasonal influenza vaccine.

What's Next?

- The U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet tomorrow, September 12th, 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.
- After the CDC Director signs off on ACIP's recommendations, Pfizer/BioNTech and Moderna will begin shipping the updated vaccines to pharmacies and other care settings in the coming days.