

COVID-19 bivalent booster vaccines – Update

- On June 30, 2022, the [FDA advised](#) manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a two component (bivalent) booster vaccine.
 - As of August 20, 2022, the omicron BA.4/BA.5 sub-lineages comprise [~93%](#) of cases in the U.S.
- Based on this guidance, on August 22, 2022, [Pfizer and BioNTech requested](#) an emergency use authorization (EUA) for a 30 µg booster dose of an omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for individuals 12 years of age and older.
 - Pre-clinical data showed a booster dose of Pfizer/BioNTech's omicron BA.4/BA.5-adapted bivalent vaccine generated a strong neutralizing antibody response against Omicron BA.1, BA.2 and BA.4/BA.5 variants, as well as the original wild-type strain. Additional data for its omicron BA.1-adapted bivalent vaccine was submitted.
 - Pfizer/BioNTech is ready to ship the bivalent booster in September as soon as authorization is granted.
- In addition, on August 23, 2022, [Moderna requested](#) an EUA for its BA.4/BA.5 omicron-targeting bivalent COVID-19 booster vaccine, mRNA-1273.222, as a 50 µg dose for adults 18 years of age and older.
 - Pre-clinical data for mRNA-1273.222 as well as clinical trial data from a phase 2/3 studying mRNA-1273.214, a bivalent booster vaccine targeting the omicron BA.1 subvariant was used to support the application.
 - Moderna is ready to ship mRNA-1273.222 in September when it is authorized.
- It is likely the FDA will not convene its [Vaccines and Related Biological Products Advisory Committee](#) and approve the booster vaccines within the next week. The Centers for Disease Control and Prevention's (CDC) [Advisory Committee for Immunization Practices \(ACIP\)](#) has scheduled meetings for September 1st and 2nd to review the data and make recommendations for use.
 - The CDC Director could sign off on the ACIP's recommendations quickly allowing for the booster vaccines to be available likely by [Labor Day](#).
- The U.S. government has purchased [66 million doses](#) of Moderna's mRNA1273.222 and up to [105 million doses](#) of Pfizer/BioNTech's BA.4/BA.5-adapted bivalent booster vaccine.
 - The [administration has informed](#) states, pharmacies and other entities that they can begin pre-ordering these bivalent vaccine doses immediately, and some [states](#) have already begun the ordering process. As soon as the vaccines are authorized, they can be immediately shipped.
 - Moderna's mRNA.1273.222's NDCs are 80777-0280-05 and 80777-0280-99. Pfizer's NDCs are not yet available.