

COVID-19 bivalent booster vaccines – Update

- On April 18, 2023, the [FDA amended](#) the emergency use authorizations (EUAs) of the [Moderna coronavirus disease 2019 \(COVID-19\) bivalent mRNA vaccine](#) and [Pfizer/BioNTech COVID-19 bivalent mRNA vaccine](#) to simplify the vaccination schedule for most individuals.
 - Both bivalent (original and omicron BA.4/BA.5 strains) vaccines are now authorized for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.
 - The monovalent Moderna and Pfizer/BioNTech COVID-19 vaccines are no longer authorized for use in the U.S.
- The recommendations from the FDA include:
 - Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
 - Most individuals who have already received a single dose of the bivalent vaccine are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.
 - Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional dose at least four months following their initial bivalent dose.
 - Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
 - Most unvaccinated individuals may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
 - Children 6 months through 5 years of age who are unvaccinated may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer/BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer/BioNTech bivalent vaccine.
 - Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.
- The use of bivalent COVID-19 vaccines for all doses administered to individuals 6 months of age and older is supported by the data submitted to the FDA, as well as post-marketing data, including real-world data, with the monovalent and bivalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children.
- Today's authorizations follow discussions that occurred during a meeting with the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on January 26. At that time, by a unanimous vote, the committee recommended harmonizing the strain composition of COVID-19 vaccines used in the U.S. There was also support for simplifying the vaccine dosing schedule.

- Refer to the EUAs for Pfizer/BioNTech and Moderna’s bivalent vaccines for specific dosing recommendations for each age group.

What’s Next:

- The Centers for Disease Control and Prevention’s (CDC) [Advisory Committee on Immunization Practices \(ACIP\)](#) will meet tomorrow, April 19th to discuss and make recommendations about the FDA amendments.
 - The Department of Health and Human Services (HHS) has already published an [operational guide](#) for Spring/Summer 2023.
- In June, the FDA will hold a meeting of its VRBPAC to discuss the strain composition of the COVID-19 vaccines for fall of 2023. Once the specific strains are selected for the COVID-19 vaccines, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.



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