

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups

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Español (<https://www.fda.gov/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-autoriza-las-vacunas-bivalentes-contr-la-covid>)

Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

These bivalent COVID-19 vaccines include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. The mRNA in these vaccines is a specific piece of genetic material that instructs cells in the body to make the distinctive “spike” protein of the original virus strain and the omicron variant lineages BA.4 and BA.5. The spike proteins of BA.4 and BA.5 are identical.

“Since children have gone back to school in person and people are resuming pre-pandemic behaviors and activities, there is the potential for increased risk of exposure to the virus that causes COVID-19. Vaccination remains the most effective measure to prevent the severe consequences of COVID-19, including hospitalization and death,” said Peter Marks, M.D., Ph.D. **“While it has largely been the case that COVID-19 tends to be less severe in children than adults, as the various waves of COVID-19 have occurred, more children have gotten sick with the disease and have been hospitalized. Children may also experience long-term effects, even following initially mild disease. We encourage parents to consider primary vaccination for children and follow-up with an updated booster dose when eligible.”**

With today’s authorization, the monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized as a booster dose for individuals five through 11 years of age. Both the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine continue to be authorized for primary series administration in individuals six months of age and older.

For each of the bivalent COVID-19 vaccines authorized today, the FDA relied on immune response and safety data that it had previously evaluated from a clinical study in adults of a booster dose of a bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of omicron lineage BA.1. The FDA considers such data as relevant and supportive of vaccines containing a component of the omicron variant BA.4 and BA.5 lineages. In addition, the FDA has evaluated and considered immune response and safety data from clinical studies of the monovalent mRNA COVID-19 vaccines, including as a booster dose in pediatric age groups. These data and real-world experience with the monovalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children, support the EUA of the bivalent COVID-19 vaccines in younger age groups.

What You Need to Know: Authorization of Moderna COVID-19 Vaccine, Bivalent

- The data supporting FDA’s authorization of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for both the 6 years through 11 years age group and 12 through 17 years age group is based on the FDA’s previous analysis of immune response and safety data from a clinical study in adults 18 years of age and older who received a booster dose of Moderna’s investigational bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of Omicron lineage BA.1.
- For the 12 through 17 years age group, the authorization is also based on the effectiveness of a single booster dose of the monovalent Moderna COVID-19 Vaccine in this age group. The FDA’s analysis included a comparison of the immune response among approximately 250 clinical trial participants in this age group who received a single booster dose of Moderna COVID-19 Vaccine at least five months after completion of a two-dose primary series of the vaccine to the immune responses among approximately 300 clinical trial participants 18 through 25 years of age who had received a two-dose primary series of Moderna COVID-19 Vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The immune response to the booster dose of Moderna COVID-19 Vaccine in the 12 through 17 years age group was comparable to the immune response to the two-dose primary series in the adult participants.
- For the 6 years through 11 years age group, the authorization is also based on the effectiveness of a single booster dose of the monovalent Moderna COVID-19 Vaccine in this age group. The FDA’s analysis included a comparison of the immune response among approximately 100 clinical trial participants 6 years through 11 years of age who received a single booster dose of Moderna COVID-19 Vaccine at least six months after completion of a two-dose primary series of the vaccine to the immune responses among approximately 300 clinical trial participants 18 through 25 years of age who had received a two-dose primary series of Moderna COVID-19 Vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The immune response to the booster dose of Moderna COVID-19 Vaccine in the 6 years through 11 years age group was comparable to the immune response to the two-dose primary series in the adult participants.
- The safety of a single booster dose of monovalent Moderna COVID-19 Vaccine was evaluated in approximately 1,300 participants 12 through 17 years of age who received a booster dose of monovalent Moderna COVID-19 Vaccine at least five months after the second dose of the primary series, and approximately 1,300 participants 6 years through 11 years of age who received a booster dose of monovalent Moderna COVID-19 Vaccine at least six months after the second dose of the primary series. The most commonly reported side effects after a booster dose of the monovalent Moderna COVID-19 Vaccine in the clinical trial participants for both age groups were pain, redness and swelling at the injection site, tiredness, headache, muscle pain, chills, joint pain, underarm swollen lymph nodes in the same arm as the injection, nausea/vomiting and fever.
- Individuals who receive the bivalent vaccine may experience similar side effects reported by individuals who received the monovalent Moderna COVID-19 Vaccine.

The data for the monovalent Moderna COVID-19 Vaccine are relevant to the Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

What You Need to Know: Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent

- The data supporting the authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 5 through 11 years of age is based in part on the FDA's previous analysis of immune response and safety data from a clinical study in adults greater than 55 years of age who received a booster dose of a Pfizer-BioNTech's investigational bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of Omicron lineage BA.1. In addition, the authorization is based on the [FDA's previous analysis \(https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose\)](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose), of safety and effectiveness data of a booster dose of monovalent Pfizer-BioNTech COVID-19 Vaccine in children 5 through 11 years of age.
- Individuals who receive Pfizer-BioNTech COVID-19 Vaccine, Bivalent may experience similar side effects reported by individuals who received the monovalent Pfizer-BioNTech COVID-19 Vaccine.

The fact sheets for both of the bivalent COVID-19 vaccines for recipients and caregivers and for healthcare providers include information about potential side effects, as well as the risks of myocarditis and pericarditis.

The amendments to the EUAs were issued to Moderna TX Inc. and Pfizer Inc.

Related Information

- [Moderna COVID-19 Vaccine \(https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine).
- [Pfizer-BioNTech COVID-19 Vaccine \(https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine).
- [COVID-19 Bivalent Vaccine Boosters \(https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccine-boosters\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccine-boosters).
- [COVID-19 Vaccines \(https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines).
- [Emergency Use Authorization for Vaccines Explained \(https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained\)](https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained).

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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