



May 20, 2022

FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children Ages 5 to 11 Years

On May 17, 2022, the U.S. Food and Drug Administration amended the [emergency use authorization \(EUA\)](#) for the Pfizer-BioNTech COVID-19 Vaccine, authorizing the use of a single booster dose for administration to children 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine. Subsequently, on May 19, 2022 the CDC's Advisory Committee on Immunization Practices ([ACIP](#)) **recommended** a single Pfizer-BioNTech COVID-19 booster dose for all children ages 5-11 years at least 5 months after the primary series. This recommendation has been approved by the CDC.

Background:

On January 3, 2022, the FDA authorized the use of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for administration to [individuals 12 through 15 years of age](#) after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine. The current action expands the use of a single booster dose of the vaccine for administration to children ages 5 through 11 years at least five months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine. **Note that this follows a two-dose primary series in 5-11yo children with a healthy immune system and follows a three-dose primary series for 5-11yo children with moderate-to-severe immune compromise.** The FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 years of age and older and has approved Comirnaty (COVID-19 Vaccine, mRNA) for use in individuals ages 16 years and older.

Data Supporting Effectiveness:

The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children ages 5 through 11 years is based on FDA's analysis of immune response data in a subset of children from the ongoing randomized placebo-controlled trial that supported the October 2021 authorization of the Pfizer-BioNTech COVID-19 Vaccine primary series in this age group. Antibody responses were evaluated in 67 study participants who received a booster dose 7 to 9 months after completing a two-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine. The antibody level against the SARS-CoV-2 virus one month after the booster dose was increased compared to before the booster dose.

FDA Evaluation of Safety

The safety of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine in this age group was assessed in approximately 400 children who received a booster dose at least five months (range 5 to 9 months) after completing a two-dose primary series. The most commonly reported side effects were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills and fever.

The FDA did not hold a meeting of its Vaccines and Related Biological Products Advisory Committee on the May 17, 2022 action, as the agency previously convened the committee for extensive discussions regarding the use of booster doses of COVID-19 vaccines and, after review of Pfizer's EUA request, the FDA concluded that the request did not raise questions that would benefit from additional discussion by committee members. Relevant FDA documents, including **updated Fact Sheets for Providers and Caregivers** are available [here](#).

References:

U.S. Food and Drug Administration. [Coronavirus \(COVID-19\) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 Through 11 Years](#). Published May 17, 2022.