FDA expands eligibility for Pfizer-BioNTech COVID-19 vaccine booster to children 5-11-years old

Today, 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 individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine.

“While it has largely been the case that COVID-19 tends to be less severe in children than adults, the omicron wave has seen more kids getting sick with the disease and being hospitalized, and children may also experience longer term effects, even following initially mild disease,” said FDA Commissioner Robert M. Califf, M.D. “The FDA is authorizing the use of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age to provide continued protection against COVID-19. Vaccination continues to be the most effective way to prevent COVID-19 and its severe consequences, and it is safe. If your child is eligible for the Pfizer-BioNTech COVID-19 Vaccine and has not yet received their primary series, getting them vaccinated can help protect them from the potentially severe consequences that can occur, such as hospitalization and death.”

On Jan. 3, 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. Today’s action expands the use of a single booster dose of the vaccine for administration to individuals 5 through 11 years

age at least five months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine. 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 16 years of age and older.

“The Pfizer-BioNTech COVID-19 Vaccine is effective in helping to prevent the most severe consequences of COVID-19 in individuals 5 years of age and older,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “Since authorizing the vaccine for children down to 5 years of age in October 2021, emerging data suggest that vaccine effectiveness against COVID-19 wanes after the second dose of the vaccine in all authorized populations. The FDA has determined that the known and potential benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age at least five months after completing a primary series outweigh its known and potential risks and that a booster dose can help provide continued protection against COVID-19 in this and older age groups.”

Data Supporting Effectiveness

The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age 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 today's 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. The FDA will make available on its website relevant documents regarding today's authorization.

The amendment to the EUA was granted to Pfizer Inc.