Booster of Pfizer/BioNTech vaccine – Expanded emergency use authorization in 5 – 11 years of age

- On May 17, 2022, the FDA announced an expanded 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.

- 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.

- 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 recommended dose of the Pfizer/BioNTech COVID-19 vaccine (orange cap) for a single booster dose in individuals 5 through 11 years of age is 0.2 mL intramuscularly administered at least 5 months after completing a primary series with the Pfizer/BioNTech COVID-19 vaccine.

    — This is the same dose (10 mcg/0.2 mL) as the primary series for the Pfizer/BioNTech COVID-19 vaccine.

- The FDA did not hold a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) 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.

What's next:

— May 19 – The Centers for Disease Control and Prevention (CDC) will convene an Advisory Committee on Immunization Practices (ACIP) meeting to discuss COVID-19 vaccinations. No agenda has been released but it could include this EUA and related recommendations.

— June 8 - FDA will convene a VRBPAC meeting to discuss use of COVID-19 vaccines in children younger than 5 years.