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Volume 64 (Issue 1652)

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COVID-19 UPDATE

Booster Dose of the Pfizer Vaccine for Children 5-11 Years Old

The FDA has expanded its Emergency Use Authorization for the mRNA COVID-19 vaccine manufactured by Pfizer/BioNTech (*Comirnaty*) to include administration of a booster dose in children 5-11 years old who completed a primary series of the Pfizer vaccine ≥ 5 months previously.¹

IMMUNOGENICITY – Expansion of the EUA was based on the results of an immunogenicity trial (summarized in the FDA Fact Sheet) in 67 children 5-11 years old who received a booster dose of the Pfizer vaccine 7-9 months after completing a 2-dose primary series. Geometric mean neutralizing antibody titer (GMT) levels against an ancestral reference strain of SARS-CoV-2 were about 10-fold higher 1 month after the booster dose than they were before it. In a population subset, GMT levels against an Omicron variant of SARS-CoV-2 (B.1.1.529) were about 22-fold higher 1 month after the booster dose than they were 1 month after the second primary-series dose.²

SAFETY – In a safety trial in 371 children 5-11 years old (summarized in the FDA Fact Sheet), injection-site pain, swelling, and erythema, fatigue, headache, muscle pain, and chills were common following administration of a booster dose of the Pfizer vaccine. The rates of these adverse effects were similar to those with primary-series doses of the vaccine. Most adverse effects were mild to moderate in severity.²

DOSAGE AND ADMINISTRATION – In children 5-11 years old, the booster dose of the Pfizer vaccine is the same as the dose for primary immunization (10 mcg IM). A single booster dose may be given ≥ 5 months after completion of a 2-dose or, in moderately or severely immunocompromised children, a 3-dose primary series.² ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA expands eligibility for Pfizer-BioNTech COVID-19 vaccine booster dose to children 5 through 11 years. May 17, 2022. Available at: <https://bit.ly/3PsFgPd>. Accessed May 23, 2022.
2. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). For 5-11 years of age. May 17, 2022. Available at: <https://bit.ly/3jX9xri>. Accessed May 23, 2022.

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