CDC and FDA Expanding Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years.

On May 19, the US Centers for Disease Control and Prevention (CDC) accepted the recommendation of the Advisory Committee on Immunization Practices (ACIP) and issued a recommendation that children ages 5 through 11 years should receive a COVID-19 booster dose at least 5 months after their initial 2-dose Pfizer-BioNTech vaccination series. Earlier in the week the US Food and Drug Administration (FDA) extended the emergency use authorization (EUA) of the pediatric Pfizer vaccine to include booster doses in this age group.

The dose for Pfizer booster shots in 5-11 year olds is the same as the primary series dose in this age group. It comes in an orange-topped multi-dose vial, is given as a 0.2 mL injection (after dilution), and contains 10 mcg of mRNA vaccine.

In addition, the CDC strengthened its recommendation that those 12 and older who are immunocompromised and everyone 50 and older should receive a second booster dose at least 4 months after their first.

Safety and Effectiveness
The EUA for this single booster dose of the Pfizer 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 clinical trials.

According to the FDA, since authorizing the vaccine for children down to 5 years of age in October 2021, emerging data suggest that vaccine effectiveness against COVID-19 partially wanes after the second dose of the vaccine in all authorized populations. The known and potential benefits of this single Pfizer booster dose can help provide continued protection against COVID-19 in this and older age groups.

The most commonly reported side effects were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain, chills and fever.

Related Information
- Pfizer-BioNTech COVID-19 Vaccine
- COVID-19 Vaccines
- Emergency Use Authorization for Vaccines Explained

Updated FDA Pfizer-BIONTECH COVID-19 Vaccine Age 5-11 Factsheets
Fact Sheet for Providers: https://www.fda.gov/media/153714/download
Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/153717/download

Reporting Adverse Events
LDH reminds providers to report possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.

If you have vaccine-related questions, please contact la.immunization@la.gov

Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues can call the Louisiana COVID Community Hotline at 855-453-0774.