Pfizer/BioNTech COVID-19 Vaccine – Expanded emergency use authorization

- On October 29, 2021, the FDA announced an expanded emergency use authorization (EUA) for the Pfizer/BioNTech COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 – 11 years of age.
    - In addition, the Pfizer/BioNTech COVID-19 vaccine is under an EUA for individuals 12 to 15 years of age.
    - Pfizer/BioNTech's Comirnaty® (COVID-19 vaccine, mRNA) is FDA approved for individuals 16 years and older.

- The effectiveness data to support the EUA is based on an ongoing randomized, placebo-controlled study that has enrolled approximately 4,700 children 5 through 11 years of age. The FDA analyzed data that compared the immune response of 264 participants from this study (received 2 doses of 10 mcg) to 253 participants 16 through 25 years of age who had two higher doses of the vaccine (2 doses of 30 mcg) in a previous study which determined the vaccine to be effective in preventing COVID-19.
    - The immune responses of the younger age participants (5 – 11 years of age) were comparable to the immune responses in older participants.
    - In addition, the FDA conducted a preliminary analysis of cases of COVID-19 occurring seven days after the second dose. In this analysis, 3 cases of COVID-19 occurred among 1,305 vaccine recipients and 16 cases of COVID-19 occurred among 663 placebo recipients; **the vaccine was 90.7% effective in preventing COVID-19**.

- The available safety data to support the EUA include more than 4,600 participants (3,100 vaccine, 1,538 placebo) ages 5 through 11 years enrolled in the ongoing study. In this trial, a total of 1,444 vaccine recipients were followed for safety for at least 2 months after the second dose.
    - Commonly reported side effects included injection site pain, redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite.
    - More children reported side effects after the second dose than after the first dose.

- Previously identified increased risks of myocarditis and pericarditis with highest risk in males 12-17 years of age have been identified by FDA and CDC surveillance systems.
    - The FDA conducted a benefit-risk assessment and determined the benefits of the vaccine would outweigh its risks in children 5 through 11 years of age.
    - Pfizer, the FDA and CDC will continue ongoing safety monitoring to include evaluation of myocarditis, pericarditis and other events of interest in children 5 to 11 years of age.

- The recommended dose of Pfizer/BioNTech's COVID-19 vaccine for individuals 5 to 11 years of age is two doses of 10 mcg (0.2 mL) given intramuscularly (IM) 21 days apart.
    - The recommended dose in individuals ages 12 years and older is two doses of 30 mcg given IM 21 days apart.

- **Special formulation for children:** The Pfizer/BioNTech COVID-19 vaccine for individuals 5-11 years of age is supplied in a multiple dose vial with an orange cap and a label with an orange

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border. The vial labels state: Age 5y to <12y. The carton labels state: For age 5 years to <12 years. The NDCs are 59267-1055-01, 59267-1055-02, and 59267-1055-04.

- The pediatric formulation uses a different buffer, Tris, that maintains pH and provides for greater stability of the product compared to Comirnaty, which uses PBS as a buffer.
- The Tris formulation can be stored at 2 – 8 degrees C for up to 10 weeks and does not require the same level of minus 90 to 60 degrees C required for Comirnaty.
- Pfizer/BioNTech COVID-19 vaccine that is supplied in vials with purple caps should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

What's Next:

- The CDC's Advisory Committee on Immunization Practices (ACIP) will meet on November 2nd to discuss Pfizer/BioNTech's COVID-19 vaccine for children 5 to < 12 years of age.

- As a reminder of the process, FDA issues the authorization, ACIP reviews the data and recommends the proper use, the CDC Director must then verify the ACIP recommendations before they become official.