Pfizer/BioNTech and Moderna COVID-19 vaccines – Expanded emergency use authorization and ACIP recommendations

- On November 19, 2021, the FDA announced an expanded emergency use authorization (EUA) for Pfizer/BioNTech and Moderna COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older at least six-months after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.

- This new approval expands the patient population eligible for booster doses. Prior recommendations for booster doses of the Pfizer/BioNTech (30 mcg) and Moderna (50 mcg) COVID-19 vaccines were for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19 and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2, as well as eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine.

- The expanded EUA is based on the FDA's analysis of immune response data that supported use in the previously authorized populations for boosters.

    — For the Pfizer-BioNTech COVID-19 vaccine booster dose, the FDA analyzed the immune response data from approximately 200 participants 18 through 55 years of age who received a single booster dose about six months after their second dose. The antibody response against the SARS-CoV-2 virus one month after a booster dose of the vaccine when compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.
    — For the Moderna COVID-19 vaccine booster dose, the FDA analyzed the immune response data from 149 participants 18 years of age and older from the original clinical studies who received a booster dose at least six months after their second dose and compared it to the immune responses of 1,055 study participants after completing their two-dose series. The antibody response against the SARS-CoV-2 virus 29 days after a booster dose of the vaccine demonstrated a booster response.

- In addition, the FDA has determined that the benefits of a single booster dose of either the Moderna or Pfizer/BioNTech COVID-19 vaccines outweigh the risks of myocarditis and pericarditis in individuals age 18 years of age and older when used following completion of primary vaccination to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.

Advisory Committee on Immunization Practices (ACIP) recommendations:

- The CDC's ACIP met on November 19, 2021 to discuss the expanded EUA for Pfizer/BioNTech and Moderna COVID-19 vaccines as a single booster dose in individuals 18 years and older after completion of a primary vaccination series.

- After extensive discussion regarding efficacy and safety regarding the booster doses, ACIP unanimously voted for the following recommendation:

    — A single COVID-19 vaccine booster dose is recommended for persons ≥18 years who received an mRNA COVID-19 vaccine primary series based on individual benefit and risk, at least 6 months after the primary series, under the FDA's EUA.

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- 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.

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