2nd booster of Pfizer/BioNTech and Moderna COVID-19 vaccines – Expanded emergency use authorization

- On March 29, 2022, the FDA announced an expanded emergency use authorization (EUA) for Pfizer/BioNTech and Moderna COVID-19 vaccines authorizing use of a second booster dose that *may* be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.

- In addition, the FDA also amended the EUAs for Pfizer/BioNTech and Moderna's COVID-19 vaccines authorizing a second booster dose *may* be administered to individuals 12 years of age and older and 18 years of age and older, respectively, with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.

    — The EUA Fact Sheets further define "immunocompromise" as individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise

- The expanded EUAs are based on safety and immune response information provided to the agency as well as additional information on effectiveness submitted by the companies.

- In an open-label, non-randomized study in 274 patients in Israel, a second booster dose of Pfizer/BioNTech or Moderna COVID-19 vaccine was administered at least four months after the first booster dose. Increases in neutralizing antibody levels against SARS-CoV-2 virus, including Delta and Omicron variants were reported two weeks after the second booster as compared to 5 months after the first booster dose.

- In addition, the FDA has determined that the known and potential benefits of a second COVID-19 vaccine booster dose with either of these vaccines outweigh their known and potential risks in these populations.

- Updated EUA Fact Sheets are available for the Pfizer/BioNTech vaccine (found here) and the Moderna vaccine (found here).

What's Next?

- The Centers for Disease Control and Prevention (CDC) must approve the FDA's recommendations for a second booster dose. An Advisory Committee on Immunization Practices (ACIP) meeting has not been scheduled yet.

- A Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting has been scheduled for April 6, 2022 to discuss considerations for use of COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants. The VRBPAC does not plan to vote on FDA's authorization for the second booster dose. Rather, the VRBPAC will discuss a general framework that will guide regulatory decision-making about the next wave of COVID-19 vaccine boosters.