

COVID-19 Vaccines – FDA Authorizes Pfizer Booster and ACIP Review (Day 2)

- On September 22, 2021 [the FDA authorized booster doses](#) of the Pfizer-BioNTech COVID-19 vaccine for certain populations. The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to allow for use of a single booster dose of Comirnaty administered at least six months after completion of the primary series. The eligible population includes:
 - 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 whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.
- This authorization applies only to the Pfizer-BioNTech COVID-19 vaccine following the initial 2-dose primary series. It does not apply to individuals who received the Moderna or Janssen COVID-19 vaccines. No data exists yet about mixing and matching the available COVID-19 vaccines.
- The [Center for Disease Control and Prevention's \(CDC's\) Advisory Committee on Immunization Practices \(ACIP\)](#) met on September 23, 2021 to discuss the updated EUA and to issue recommendations for use.
- The ACIP members evaluated the available data to estimate the risks and benefits of giving a booster dose in various populations and situations. Multiple members reaffirmed that the current vaccines, including the Pfizer-BioNTech vaccine, are highly effective. Some individuals experience waning immunity but not everyone will need a booster dose.
- ACIP stated that a single booster dose of the Pfizer-BioNTech vaccine is recommended in persons:
 - Aged \geq 65 years, and long-term care facility residence, at least 6 months after the primary series with the Pfizer-BioNTech vaccine under the FDA's EUA.
 - Aged 50 to 64 years with underlying medical conditions, at least 6 months after the primary series with the Pfizer-BioNTech vaccine under the FDA's EUA.
 - Based on individual benefit and risk in individuals who are age 18 to 49 years with underlying medical conditions at least 6 months after the primary series with the Pfizer-BioNTech vaccine under the FDA's EUA.
- The ACIP also discussed use in institutional or occupational settings where risk of COVID-19 is high (homeless shelters, prisons, health care settings), but the majority of members believed the evidence was not sufficient to make a recommendation. An additional meeting to further discuss this issue as well as emerging data is expected in the coming weeks.
- The FDA is reviewing boosters for the Moderna COVID-19 vaccine, but no data is yet available and a decision date has not been set.