

**Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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FDA Amends EUA for COMIRNATY/Pfizer-BioNTech and Moderna mRNA Vaccines and CDC/ACIP Endorses New Recommendations

On January 3, 2022, after a thorough and ongoing review of the available safety and efficacy data in the setting of surging COVID-19 cases in adults and children, the United States Food and Drug Administration (FDA) revised the emergency use authorizations (EUA) for both the COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine. The CDC, along with its Advisory Committee on Immunization Practice, subsequently endorsed the FDA's decisions.

The three revisions to the original letter of authorization are as follows:

- 1. To authorize the use of the Pfizer-BioNTech vaccine as a single booster dose in individuals 12 through 15 years of age.** The FDA and ACIP determined that the continued protection against COVID-19 and the associated serious consequences that can occur, including hospitalization and death, afforded by a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine outweigh the potential risks in individuals 12 through 15 years of age. Previously, the booster dose of the vaccine was authorized for those 16 years of age and older. The ACIP now recommends that all individuals 12 years of age and older get an applicable booster dose of vaccine.
- 2. To lower the authorized dosing interval of a COVID-19 vaccine booster dose to at least five (5) months after completion of a Pfizer-BioNTech or Moderna primary series.** Based on mounting evidence that a booster dose of the COVID-19 vaccine is critical for protection against the rapidly spreading omicron variant and that the ongoing safety data review has revealed no new significant adverse events or safety concerns, the FDA and ACIP has determined that the known and potential benefits of administering a booster at least five (5) months following completion of a mRNA primary vaccination series to individuals ages 12 and older for the Pfizer product and those 18 and older for Moderna outweighs the known and potential risks. The booster dose after the Johnson & Johnson/Janssen vaccine remains at two (2) months. The mRNA vaccine product continues to be preferred for the primary series and the booster dose and the booster dose may be heterologous.
- 3. To authorize a third primary series dose of the Pfizer-BioNTech vaccine administered at least 28 days following the two-dose regimen of this vaccine in individuals 5 through 11 years of age who are determined to be moderately to severely immunocompromised.** Previously, the vaccine was authorized only for those 12 years of age and older with an immunocompromising condition. Again, the agency determined that the potential benefits of the administration of a third primary series dose at least 28 days following the second dose of the two-dose regimen, outweighed the potential and known risks of the vaccine in this group of children. No changes were made to the previously authorized use of the vaccine for those 12 years of age and older with immunocompromise.

No updates were made for the Johnson & Johnson/Janssen vaccine, although a continuous review of the data is ongoing. Providers should refer to the CDC's latest news release and Clinical Considerations page for complete details.

For Additional Information

1. <https://www.fda.gov/media/150386/download>
2. <https://www.cdc.gov/media/releases/2022/s0105-Booster-Shot.html>
3. <https://www.cdc.gov/media/releases/2022/s0104-Pfizer-Booster.html>
4. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
5. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months>