

**CDC/DDID/NCIRD**

December 8, 2022

DECISION REQUESTED**Recommendations:**

The Centers for Disease Control and Prevention (CDC) endorses the following within the parameters of the Emergency Use Authorizations (EUA) issued by the Food and Drug Administration (FDA):

- A single booster dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/A.5) is recommended for children ages 6 months through 5 years at least 2 months after completion of a Moderna COVID-19 vaccine primary series.
- A third primary series dose of Pfizer-BioNTech Vaccine COVID-19, Bivalent (Original and Omicron BA.4/BA.5) is recommended for children ages 6 months through 4 years at least 8 weeks after receipt of a second dose of monovalent Pfizer-BioNTech COVID-19 vaccine primary series.

CDC repeals its previous recommendation for administration of monovalent Pfizer-BioNTech COVID-19 Vaccine as a third primary series dose for children ages 6 months through 4 years.

Status Quo Ante:

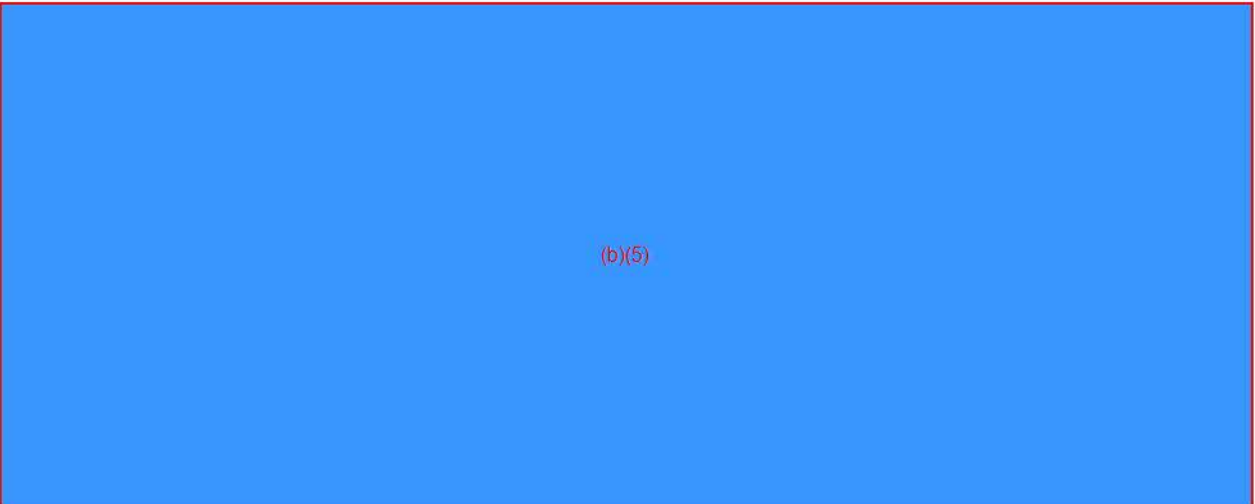
- ACIP has issued recommendations for COVID-19 vaccination for everyone ages 6 months and older for the prevention of COVID-19 in the United States.
- ACIP recommended everyone ages ≥ 5 years should get 1 COVID-19 vaccine bivalent booster dose at least 2 months after completing their COVID-19 vaccine primary series or receiving a previous monovalent COVID-19 vaccine booster dose.
- On December 8, 2022, FDA amended the EUA for the Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/A.5) to authorize the use of a single bivalent booster dose for administration to children ages 6 months through 5 years at least 2 months after completion of a Moderna COVID-19 vaccine primary series.
- On December 8, 2022, FDA amended the EUA for the Pfizer-BioNTech Vaccine COVID-19, Bivalent (Original and Omicron BA.4/BA.5) to authorize the use of a third primary series dose for children ages 6 months through 4 years at least 8 weeks after receipt of the second dose of a monovalent Pfizer-BioNTech COVID-19 vaccine primary series.

Key Issues:

- As of November 2022, over 98 million COVID-19 cases and over 1 million COVID-19 deaths have been reported in the United States.
- Through November 30, 2022, 6.0% of children <2 years of age and 8.6% of children 2 through 4 years of age have received at least one dose of COVID-19 vaccine; 2.1% of children <2 years of age and 3.9% of children 2 through 4 years of age have completed a primary series.

- Approximately 450,000 children (~2% of children ages 6 months through 5 years) have completed a 2-dose Moderna COVID-19 vaccine primary series and would be eligible for a booster dose.
- Approximately 400,000 children (~2% of children ages 6 months through 4 years) have received 2 doses of the 3-dose Pfizer-BioNTech COVID-19 vaccine primary series and would be eligible for a bivalent third primary series dose.
- Studies in adults demonstrated that a bivalent booster dose of either Moderna or Pfizer-BioNTech COVID-19 vaccine broadens the immune response in those who have completed a primary series and a previous booster dose.
 - Compared with a monovalent booster dose (based on the ancestral strain of SARS-CoV-2), there was a demonstrated superior response to Omicron and a demonstrated non-inferior response to the ancestral strain.
- Monovalent booster doses for Moderna COVID-19 vaccines were studied in clinical trials with 145 children ages 6 months through 5 years who had completed a Moderna primary series 8–13 months previously (median: 10 months).
 - Reactogenicity symptoms were similar to what have been seen for booster doses in other age groups.
 - Antibody levels after the monovalent booster dose in a subset of children 6 months through 5 years of age without prior SARS-CoV-2 infection (N=56) were 4 times higher than what was seen after the primary series in young adults.
- Antibody levels after three doses of monovalent Pfizer-BioNTech COVID-19 vaccine in children ages 6 months through 4 years were similar to antibody levels observed in individuals ages 16 through 24 years after two doses of the monovalent Pfizer-BioNTech vaccine.
 - No data are available for a mixed monovalent-bivalent Pfizer-BioNTech COVID-19 primary series in this age group.

Pros:

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Cons:

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Next Steps:

- If this recommendation is adopted by the CDC Director, CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States," clinical education materials and related webpages will be updated.

Recommendations:

CDC endorses that children ages 6 months through 5 years who have completed a Moderna COVID-19 vaccine primary series receive a single Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/A.5) booster dose at least 2 months after completion of the Moderna COVID-19 vaccine primary series.

In addition, CDC endorses that the third dose of the Pfizer-BioNTech COVID-19 vaccine primary series for children ages 6 months through 4 years consist of a Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) dose, at least 8 weeks after the second primary series dose.

Approved: X **Not Approved:** **Would like briefing:**



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