Moderna and Pfizer/BioNTech COVID-19 vaccines, bivalent authorized down to 6 months old – Updated emergency use authorizations

- All individuals seeking a Moderna COVID-19 booster who are age 6 months and older should receive the Moderna bivalent vaccine.

- Individuals 6 months to 4 years of age seeking a third dose of the Pfizer/BioNTech vaccination series should receive the Pfizer/BioNTech bivalent vaccine instead of the monovalent third dose.

- The new bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variants.

- On December 8, 2022, the FDA announced the amended emergency use authorization (EUA) of two COVID-19 vaccines: Moderna's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5) and Pfizer/BioNTech's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5), authorized as a single booster dose for active immunization to prevent coronavirus disease 2019 (COVID-19) in individuals 6 months of age and older.

    - Moderna COVID-19 vaccine, bivalent is now authorized as a booster dose in individuals 6 months of age and older. Previously, it was authorized in individuals 6 years of age and older.
    - Pfizer/BioNTech COVID-19 vaccine, bivalent is authorized as a substitute for the 3rd dose of the monovalent COVID-19 vaccine in individuals 6 months of age to 4 years of age.
    - With today's authorization, the previously authorized monovalent Pfizer/BioNTech mRNA COVID-19 vaccine, is no longer authorized as a third dose for individuals 6 months to 4 years of age.
    - Mix-and-match use is NOT authorized because of the different recommendations for each manufacturer.

- The authorized bivalent COVID-19 vaccines, or updated boosters, include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component for the BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. The spike proteins for BA.4 and BA.5 variants are identical.

- For each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including:

    - Safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines,
    - Safety and immunogenicity data from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1 lineage that is similar to each of the vaccines being authorized,
    - Nonclinical data from the bivalent COVID-19 vaccines containing mRNA of the original strain and the omicron variant (BA.4/BA.5)

- Warnings and precautions include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.

- Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA COVID-19 vaccines.

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Current Authorized Vaccine Schedules

- **Pfizer/BioNTech COVID-19 monovalent vaccine and Pfizer/BioNTech COVID-19, bivalent**: The recommended dose in individuals 6 months to 4 years of age is administered intramuscularly (IM) as two doses (0.2 mL) of the monovalent vaccine 3 weeks apart followed by 0.2 mL IM of the bivalent vaccine at 8 weeks after the 2nd dose of the monovalent vaccine.

    — The Pfizer COVID-19 vaccine, monovalent is supplied in multiple-dose vials with a maroon cap and a label with a maroon border and says Age 2y to < 5y or Age 6m to < 5y. NDCs: 59267-0078-01 and 59267-0078-02
    — The Pfizer COVID-19 vaccine, bivalent is supplied in multiple-dose vials with a maroon cap and a label with a maroon border and says Age 6m to < 5y. NDCs: 59267-0609-01 and 59267-0609-02.

- **Moderna COVID-19 vaccine, bivalent:** The recommended dose in individuals 6 months to 5 years of age is administered IM as a single booster dose (0.2 mL) at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

    — The Moderna COVID-19 vaccine, bivalent is supplied in multiple-dose vials with a dark pink cap and a label with a yellow box saying Booster Doses Only Age 6mthrough 5y. NDC 80777-0283-02.

What's Next?

- The Centers for Disease Control and Prevention (CDC) Director will need to sign off on the approval by the FDA. It has not been announced if the CDC's Advisory Committee on Immunization Practices (ACIP) will meet to discuss the FDA approval and make further recommendations.

- The U.S. government has already purchased bivalent booster doses for children. The Pfizer/BioNTech and Moderna bivalent vaccine vials for children have been available for pre-ordering.

- Pharmacies and other administration sites may begin administering bivalent booster vaccine to appropriate children when they have supply.

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