LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-30: FDA Authorizes and CDC Recommends Updated COVID-19 Vaccine Boosters Targeted to be More Effective Against Current Variants**
Origination Date: *September 2, 2022*	**Revision Dates (List All Revision Dates):**

FDA Authorizes and CDC Recommends Updated COVID-19 Vaccine Boosters Targeted to be More Effective Against Current Variants

This week, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) authorized bivalent formulations of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for use as a single booster dose at least two months following primary or booster vaccination. These updated boosters are formulated to offer continued protection against the ancestral strain while also offering better protection against two lineages of the omicron variant, BA.4 and BA.5, which represent over 90% of currently circulating virus.

This FDA action is for Emergency Use Authorization (EUA) of these two bivalent mRNA COVID-19 vaccines:

- The Moderna COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 18 years of age and older.
- The Pfizer-BioNTech COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 12 years of age and older.

“Mix and matching” of the new bivalent booster dose is allowed; one may receive either the Pfizer or Moderna product regardless of which product they received for their primary series and/or prior booster dose.

Both of the authorized bivalent COVID-19 vaccines include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. In June, the FDA’s Vaccines and Related Biological Products Advisory Committee voted overwhelmingly to include an omicron component in COVID-19 booster vaccines.

With authorization of these two bivalent vaccines, the original monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older.

Who is eligible to receive the bivalent single dose booster dose?

- **Moderna:** Individuals 18 years of age and older are eligible for a single bivalent booster dose if it has been at least two months since they have completed the primary vaccination series or since they received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- **Pfizer-BioNTech:** Individuals 12 years of age and older are eligible for a single bivalent booster dose if it has been at least two months since they have completed the primary vaccination series or since they received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Note: EUA language lists the current interval to be generally at least two months from last COVID-19 vaccination, so please stand-by for more specific interval information that may be included in soon to be updated CDC Interim Clinical Considerations.

Vaccine Safety and Effectiveness
The bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variants. For each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including:

- Extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines,
- Safety and immunogenicity data obtained 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, and
- Nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant.

Side Effects
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.

Where and how can families get their children vaccinated?

Ordering the Bivalent COVID-19 doses
The bivalent doses are currently available for order for providers enrolled in the Louisiana COVID-19 Vaccine Program. For those who have not placed orders, this can be done online at LINKS Louisiana Immunization Network. If you are not an enrolled in the Louisiana COVID-19 Vaccine Program, and would like to administer bivalent vaccinations, contact la.links@la.gov .

FDA Fact Sheets

- Pfizer fact sheet for providers: https://www.fda.gov/media/157233/download
- Pfizer fact sheet for recipients/caregivers: https://www.fda.gov/media/153716/download
- Moderna fact sheet for providers: https://www.fda.gov/media/161318/download
- Moderna fact sheet for recipients/caregivers: https://www.fda.gov/media/144638/download

Additional Reference Materials

- Moderna COVID-19 Vaccine
- Pfizer-BioNTech COVID-19 Vaccine
- COVID-19 Bivalent Vaccine Boosters
- COVID-19 Vaccines
- Emergency Use Authorization for Vaccines Explained

Reporting Adverse Events

LDH reminds providers to report possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.

If you have vaccine-related questions, please contact la.immunization@la.gov . Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues, can call the Louisiana COVID-19 Community Hotline at 855-453-0774.