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FDA Authorizes Changes to Bivalent mRNA COVID-19 Vaccines
Monovalent COVID-19 vaccines no longer authorized for use

Today, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. **The monovalent COVID-19 vaccines are no longer authorized for use as of April 18, 2023**.

Background

Data support simplifying the use of the authorized mRNA bivalent COVID-19 vaccines. Evidence is now available that most of the U.S. population 5 years of age and older now have antibodies as a result of either vaccination or infection against SARS-CoV-2, which can serve as a foundation for the protection provided by the bivalent vaccines. COVID-19 continues to be a very real risk for many people, and individuals are encouraged to stay current with vaccination, including with a bivalent COVID-19 vaccine. Data continue to demonstrate that vaccines prevent the most serious outcomes of COVID-19, which are severe illness, hospitalization, and death.

Updated COVID-19 vaccination recommendations (FDA)

Here is the FDA overview of who is currently eligible to receive bivalent COVID-19 vaccine(s):

- **Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine** who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.

- **Most individuals who have already received a single dose of the bivalent vaccine** are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.

- **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine** may receive one additional dose at least four months following their initial bivalent dose.

- **Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine** may receive a single additional dose of a bivalent COVID-19

vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.

- **Most unvaccinated individuals** may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.

- **Children 6 months through 5 years of age who are unvaccinated** may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.

- **Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine** may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.

For more information

- Full FDA announcement: www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines?utm_medium=email&utm_source=govdelivery

- Local information about COVID-19: www.slopublichealth.org/covid19