

FDA NEWS RELEASE

FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants

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Español (<https://www.fda.gov/news-events/press-announcements/la-fda-emprende-acciones-con-respecto-las-vacunas-contr-el-covid-19-de-arnm-actualizadas-para>)

Today, the U.S. Food and Drug Administration took action approving and authorizing for emergency use updated COVID-19 vaccines formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. Today’s actions relate to updated mRNA vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc. Consistent with the totality of the evidence (<https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023>) and input from the FDA’s expert advisors, these vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.

What You Need to Know

- **Individuals 5 years of age and older regardless of previous vaccination** are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months since the last dose of any COVID-19 vaccine.
- **Individuals 6 months through 4 years of age who have previously been vaccinated** against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- **Unvaccinated individuals 6 months through 4 years of age** are eligible to receive three doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated authorized Moderna COVID-19 Vaccine.
- The FDA is confident in the safety and effectiveness of these updated vaccines and the agency’s benefit-risk assessment demonstrates that the benefits of these vaccines for individuals 6 months of age and older outweigh their risks.
- Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines as described in the respective prescribing information or fact sheets.
- The updated vaccines are expected to provide good protection against COVID-19 from the currently circulating variants. Barring the emergence of a markedly more virulent variant, the FDA anticipates that the composition of COVID-19 vaccines may need to be updated annually, as is done for the seasonal influenza vaccine.
- The U.S. Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices will meet tomorrow (Sept. 12), to discuss clinical recommendations on who should receive an updated vaccine, as well as further considerations for specific populations such as immunocompromised and older individuals.
- Manufacturers have publicly announced that the updated vaccines would be ready this fall, and the FDA anticipates that the updated vaccines will be available in the near future.

“Vaccination remains critical to public health and continued protection against serious consequences of COVID-19, including hospitalization and death,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “The public can be assured that these updated vaccines have met the agency’s rigorous scientific standards for safety, effectiveness, and manufacturing quality. We very much encourage those who are eligible to consider getting vaccinated.”

The updated mRNA vaccines are each approved for individuals 12 years of age and older and are authorized under emergency use for individuals 6 months through 11 years of age. As part of today’s actions, the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Data Supporting the Updated mRNA COVID-19 Vaccines (2023-2024 Formula)

The mRNA COVID-19 vaccines approved and authorized today are supported by the FDA’s evaluation of manufacturing data to support the change to the 2023-2024 formula and non-clinical immune response data on the updated formulations including the XBB.1.5 component.

- The updated mRNA vaccines are manufactured using a similar process as previous formulations. In studies that have been recently conducted, the extent of neutralization observed by the updated vaccines against currently circulating viral variants causing COVID-19, including EG.5 and BA.2.86, appears to be of a similar magnitude to the extent of neutralization observed with prior versions of the vaccines against corresponding prior variants against which they had been developed to provide protection. This suggests that the vaccines are a good match for protecting against the currently circulating COVID-19 variants.
- The benefit-risk profile of previously authorized and approved mRNA COVID-19 vaccines is well understood as these vaccines have been administered to hundreds of millions of people in the United States.

BioNTech-Pfizer Exhibit 1110
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Based on an evaluation of the totality of the evidence, the benefit-risk profile is favorable for individuals 6 months of age and older to receive an updated COVID-19 mRNA vaccine. Although serious outcomes from COVID-19 are less common in younger individuals, they do occur, and it has been demonstrated that recently receiving a COVID-19 vaccine reduces the risk of such serious outcomes.

Additional Details on Today’s Actions

Specifically, today’s actions include:

- Approval of Comirnaty (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, and a change to a single dose for individuals 12 years of age and older. Comirnaty was previously approved as a two-dose series for individuals 12 years of age and older.
- Approval of Spikevax (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, a change to a single dose for individuals 18 years of age and older, and approval of a single dose for individuals 12 through 17 years of age. Spikevax was previously approved as a two-dose series for individuals 18 years of age and older.
- Authorization of Moderna COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula and lower the age eligibility for receipt of a single dose from 6 years to 5 years of age. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.
- Authorization of Pfizer-BioNTech COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.

The approval of Comirnaty (COVID-19 Vaccine, mRNA) (2023-2024 Formula) was granted to BioNTech Manufacturing GmbH. The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) was issued to Pfizer Inc.

The approval of Spikevax (COVID-19 Vaccine, mRNA) (2023-2024 Formula) was granted to ModernaTX Inc. and the EUA amendment for the Moderna COVID-19 Vaccine (2023-2024 Formula) was issued to ModernaTX Inc.

Related Information

- [Comirnaty \(https://www.fda.gov/vaccines-blood-biologics/comirnaty\)](https://www.fda.gov/vaccines-blood-biologics/comirnaty) (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- [Spikevax \(https://www.fda.gov/vaccines-blood-biologics/spikevax\)](https://www.fda.gov/vaccines-blood-biologics/spikevax) (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- [Moderna COVID-19 Vaccine \(https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/moderna-covid-19-vaccines\)](https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/moderna-covid-19-vaccines) (2023-2024 Formula)
- [FDA Resources for the Fall Respiratory Illness Season \(https://www.fda.gov/fallvaccines\)](https://www.fda.gov/fallvaccines)
- [Pfizer-BioNTech COVID-19 Vaccine \(https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines\)](https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines) (2023-2024 Formula)
- [Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2023 \(https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023\)](https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023)
- [June 15, 2023, Meeting of the Vaccines and Related Biological Products Advisory Committee \(https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement\)](https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement)

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Inquiries

Media:

✉ [FDA Office of Media Affairs \(mailto:FDAOMA@fda.hhs.gov\)](mailto:FDAOMA@fda.hhs.gov)

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