

FDA approves updated COVID shots for fall

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Updated shots you may soon get to shield against COVID-19 infection were approved by the U.S. Food and Drug Administration on Thursday.

This year's approval for the updated mRNA vaccines comes much sooner than happened in 2023, when fall vaccines were authorized on



Sept. 11.

The latest shots from Moderna and Pfizer will now target a variant of the omicron strain of the virus called KP.2, the FDA said in a statement.

"The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death," the FDA said.

The agency had already told Moderna and Pfizer in June that the JN.1 lineage of SARS-Cov-2 should be the autumn shots' target, and then more specifically the KP.2 strain.

According to data from the Centers for Disease Control and Prevention, the prevalent COVID variant is now KP.3.1.1, thought to make up 37% of cases over the past two weeks.

KP.3.1.1 and KP.2, which are covered by the updated shots, are offshoots of JN.1. All are members of the omicron family.

"Vaccination continues to be the cornerstone of COVID-19 prevention," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in the statement.

"These updated vaccines meet the agency's rigorous, scientific standards for safety, effectiveness and manufacturing quality," he added. "Given the waning immunity of the population from previous exposure to the virus and from prior vaccination, we strongly encourage those who are eligible to consider receiving an updated COVID-19 vaccine to provide better protection against currently circulating variants."

The Moderna and Pfizer vaccines are currently recommended for use by



everyone aged 6 months and older. The guidelines for use by vaccination status or age are:

- Unvaccinated small children: Between 6 months and 4 years of age, this group should receive three doses of the updated Pfizer vaccine or two doses of the updated Moderna vaccine.
- Previously vaccinated small children: One or two doses of either vaccine, depending on the previous COVID vaccine the child received.
- Children ages 5 through 11: Regardless of prior vaccination status, a single dose of either the updated Moderna or Pfizer vaccine should be given. If previously vaccinated, the new dose should be given at least two months after the last shot.
- People ages 12 and older: A single dose of the newly updated and approved Moderna or Pfizer vaccines. If previously vaccinated, the new dose should be given at least two months after the last shot.
- Immunocompromised individuals: Additional doses are authorized for children between the ages of 6 and 11, as described in fact sheets accompanying the vaccines.

"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," the FDA said.

The agency added that "the updated vaccines are expected to provide protection against COVID-19 caused by the currently circulating variants," and the new shots are manufactured using the same processes as prior vaccines.

"The mRNA COVID-19 vaccines have been administered to hundreds of millions of people in the U.S., and the benefits of these vaccines continue to outweigh their risks," the FDA stressed.



Thursday's approval comes as Americans are suffering through a summer surge of COVID cases—the highest seen since the summer of 2022, based on wastewater levels of virus tracked by the U.S. Centers for Disease Control and Prevention.

Still, experts note that although levels of severe disease have been rising, they remain much lower than those seen during the early years of the pandemic.

Both Moderna and Pfizer have said they have ample supplies of their updated COVID vaccines on hand, ready for shipment to stores soon after FDA approval. If approved, the Novavax <u>vaccine</u> may take a bit longer to reach consumers, because its protein-based shot takes more time to manufacture than mRNA vaccines do.

In June, the CDC recommended that every American over the age of 6 months receive an updated COVID-19 shot along with the flu shot this year.

More information: Find out more about the COVID vaccine at the <u>Mayo Clinic</u>.

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