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FDA Grants Full Approval of Pfizer-BioNTech COVID-19 Vaccine

Full approval could encourage more people to get vaccinated and raises the prospect of off-label use.

August 23, 2021 By Liz Highleyman

On August 23, the Food and Drug Administration (FDA) granted full approval of the Pfizer-BioNTech COVID-19 vaccine. This is the first vaccine for SARS-CoV-2, the virus that causes COVID-19, to receive traditional approval; health officials hope the move will encourage more people to get vaccinated.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic," acting FDA Commissioner Janet Woodcock, MD, said in a statement. "While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness and manufacturing quality the FDA requires of an approved product."

> Today, FDA approved the first COVID-19 vaccine for the prevention of #COVID19 disease in individuals 16 years of age and older. https://t.co/iOqsxXV1fj
>
> — U.S. FDA (@US_FDA) August 23, 2021

The Pfizer-BioNTech vaccine was granted emergency use authorization (EUA) for people ages 16 or older on December 11, 2020. It was later authorized for teens ages 12 to 15—the only vaccine yet authorized for this group. The full approval applies only to people 16 or older, while the younger age group remains covered by the EUA. The Moderna vaccine received its EUA a week after the Pfizer-BioNTech vaccine, and many expect full approval to come soon.

The Pfizer-BioNTech vaccine, also known as BNT162b2 or Comirnaty, employs a novel messenger RNA (mRNA) technology. It uses lipid nanoparticles to deliver bits of genetic material that encode instructions for making the SARS-CoV-2 spike protein—the red protuberances in the ubiquitous virus image—which the coronavirus uses to enter human cells. When injected into a muscle, the cells produce the protein, triggering an immune response. The mRNA degrades quickly in the body, and it does not alter human genes. The Moderna vaccine uses a similar approach.

In a Phase III clinical trial, more than 43,000 adult volunteers were randomly assigned to receive either two doses of thePfizer-BioNTech vaccine three weeks apart or a placebo. The vaccine was 95% effective at reducing the risk of symptomatic COVID-19 after the second dose. Of the 10 reported cases of severe COVID-19, nine were in the placebo group.

Vaccine efficacy has declined somewhat in the face of the more transmissible SARS-CoV-2 Delta variant. Although study results vary, the vaccine still appears to be around 90% effective at preventing severe COVID-19 or death and about 80% effective against symptomatic illness. But its efficacy against any infection (which was not the endpoint in the Phase III trial) has fallen to around 50% in some studies, and there's evidence that effectiveness may decline over time.

This decline in effectiveness—in particular waning antibody levels several months after the second dose—informed the Biden administration's recent announcement that it plans to make booster doses of the Pfizer-BioNTech and Moderna vaccines available to all adults eight months after their last dose. Officials said they do not yet have enough data to recommend the same for those who received the single-shot Johnson & Johnson vaccine. Some experts, however, think the announcement was premature, and there is little evidence that healthy young people will need a booster so soon. Although antibody levels normally fall after natural infection or vaccination, memory B cells and T cells continue to provide protection.

This is separate from the FDA's recent amendment to the Pfizer-BioNTech and Moderna EUAs and the CDC's recommendation that moderately to severely immunocompromised people—for example, organ transplant recipients, people being treated for cancer and people with advanced or untreated HIV—should receive a third dose of the mRNA vaccines. In that case, rather than waning immunity, some people with a compromised immune system do not mount an adequate antibody response after two doses and can benefit from a third.

The FDA has officially approved the Pfizer COVID-19 vaccine. While all three COVID vaccines have met FDA's strict standards for emergency use, this FDA approval should give added confidence that this vaccine is safe and effective.

If you’re not vaccinated yet, now is the time.

https://t.co/XaxFdWHbRc

— President Biden (@POTUS) August 23, 2021

Officials hope the approval will encourage more people to get vaccinated. Polls have found that although some people resist vaccination for political reasons, others are hesitant because they feel the vaccines were approved too quickly and did not have full approval. (In fact, the mRNA technology has been under development for decades and was built on the foundation of HIV vaccine research.)

“While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated,” Woodcock said. “Today’s milestone puts us one step closer to altering the course of this pandemic in the U.S.”

Today’s approval could also make it easier for cities, hospitals, businesses, schools and airlines to mandate vaccination. What’s more, full approval generally allows physicians to prescribe medications and vaccines off-label as they see fit. This could mean, for example, that a doctor might prescribe a Pfizer-BioNTech dose for a person who received the J&J vaccine. Doctors may also seek to prescribe the vaccine for children under 12, but experts caution that this is not advisable before the FDA authorizes the vaccine for this group.

UPDATE: The CDC has clarified that off-label use of the Pfizer-BioNTech vaccine is “not authorized at this time.”

“Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research. “We have not lost sight that the COVID-19 public health crisis continues in the U.S. and that the public is counting on safe and effective vaccines. The public and medical community can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S.”

Click here to read the FDA announcement.
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