

FDA grants full approval to Pfizer-BioNTech's Covid vaccine

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Key Points

- The FDA granted Pfizer and BioNTech full U.S. approval of their Covid-19 vaccine.
- The move may encourage some unvaccinated Americans to get the shots as well as give more private businesses across the nation greater confidence to implement vaccine mandates.
- Up until now, the mRNA vaccine was on the U.S. market under an Emergency Use Authorization.

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FDA grants full approval for Pfizer's coronavirus vaccine

The Food and Drug Administration on Monday granted full approval to Pfizer and BioNTech's Covid-19 vaccine – becoming the first in the U.S. to win the coveted designation and giving even more businesses, schools and universities greater confidence to adopt vaccine mandates.

Up until now, the mRNA vaccine, which will be marketed as Comirnaty, was on the U.S. market under an emergency use authorization that was granted by the FDA in December. Since then, more than 204 million of the Pfizer shots have been administered, according to data compiled by the Centers for Disease Control and Prevention.

Federal health officials had been under mounting pressure from the scientific community and advocacy groups to fully approve Pfizer and BioNTech's vaccine ever since the drugmakers submitted their application to the agency in early May. The companies submitted a Biologics License Application, which secures full approval, to the FDA on May 7 for patients age 16 and up.

FDA scientists evaluated “hundreds of thousands of pages” of vaccine data from 40,000 trial participants, according to the U.S. agency. The vaccine was found to be 91% effective in preventing Covid – slightly lower than the 95% efficacy rate trial data showed when the shot was authorized late last year and before the delta variant took hold in the U.S.

Pfizer's vaccine met the agency's “high standards for safety, effectiveness, and manufacturing quality,” acting FDA Commissioner Janet Woodcock said in a statement. “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.”

The FDA held a media briefing Monday morning to discuss the approval.

Although more than 60% of the total U.S. population has had at least one dose of a Covid vaccine, many Americans say they are still hesitant about getting vaccinated, even as the highly contagious delta variant spreads. Full approval may convince some Americans that the shots are safe, doctors and epidemiologists say. In fact, a survey from the Kaiser Family Foundation found 3 in 10 unvaccinated adults said they would be more likely to get vaccinated if one of the vaccines receives full approval.

Full approval is “more psychological than anything else,” said Dr. Paul Offit, a voting member of the agency's Vaccines and Related Biological Products Advisory Committee. “I mean you already have more than 320 million doses administered that are out there. The vaccines already have an enormous safety and efficacy profile.”

U.S. approval is also likely to spur a new wave of vaccine mandates from corporate America. Major companies – from Walt Disney to Walmart – have already told some or all of their employees that they must get fully vaccinated against Covid this fall. Still, some private businesses may have felt hesitant about requiring the shots, before full approval, even though they had the legal authority to do so, said Dorit Reiss, a professor of law at UC Hastings College of the Law.

The Pentagon said it would make vaccinations mandatory for service members “no later” than the middle of September, or sooner if the FDA grants full approval earlier.

“You’re going to see the empowerment of local enterprises, giving mandates that could be colleges, universities, places of business, a whole variety and I strongly support that,” White House chief medical officer Dr. Anthony Fauci said Aug 8, when asked about full approval of the vaccines. “The time has come. ... We’ve got to go the extra step to get people vaccinated.”

Pfizer’s shot is the first Covid vaccine to receive full regulatory approval in the U.S. Federal regulators had previously said they would work as quickly as possible to clear Pfizer’s vaccines.

The vaccine is still under emergency use authorization for children 12 to 15 as the company continues to collect data. Dr. Peter Marks, the FDA’s top vaccine regulator, said Monday the agency would move as “swiftly” as possible on approving the shot for kids under 12 once the company submits the data.

“Currently, there are still trials ongoing and so the agency has to wait for the company to submit the data for those trials,” he said during a briefing. “We certainly want to make sure that we get it right.”

Marks also addressed misinformation about the shot, including that it contains microchips and causes infertility.

“We’ve heard false claims that the Covid-19 vaccine causes infertility, contains microchips and causes Covid-19. And worse, we’ve heard false claims that thousands of people have died from the vaccine,” he said. “Let me be clear: these claims are simply not true.”

Standard vaccine reviews generally take several months to a year or more to determine whether they are safe and effective for use in the general public. But due to the pandemic, which has killed more than 628,000 Americans, the FDA permitted the use of the shots under an EUA.

In a public health emergency, the manufacturing and approval of vaccines can be streamlined through emergency authorizations. Former Health Secretary Alex Azar declared a public health emergency on Jan. 31, 2020. The health emergency has been renewed several times, most recently in late July. The FDA allowed the use of the shots with just two months of safety data under an EUA. It's not the same as a Biologic License Application, or a request for full approval, which requires at least six months of data.

Before granting full approval, FDA scientists must painstakingly look through the companies' clinical trial data, including for any discrepancies or safety concerns, said Offit, who is also director of the Vaccine Education Center at the Children's Hospital of Philadelphia.

It's a lot of data, Offit said. He previously said when Merck submitted its data from its 70,000-person rotavirus vaccine trial, the pages that were generated could have exceeded the height of the Sears Tower — a 1,450-foot skyscraper in Chicago that's now known as Willis Tower.

"The FDA will do what it thinks it needs to do to make sure that the American public is safe," he said.

Full approval is also very beneficial to companies that submit an application, former FDA Commissioner Dr. Robert Califf said in a phone interview in May.

With it, Pfizer and BioNTech are now able to market the shots directly to U.S. consumers. Companies can't promote their products under an EUA, he said. It also allows the shot to stay on the market once the pandemic is over and the U.S. is no longer considered in an "emergency."

"The vaccines will still have to be administered under the supervision of a professional who's qualified," Califf said. "It's not like they can send the vaccines to people's homes. However, they can advertise on TV and promote their products under the watchful eye of the FDA."

Pfizer and BioNTech have said they expect to generate billions from the vaccine. Under full approval, the companies could also decide to charge more for the vaccines, health experts say.

The companies have already raised the price of their vaccine in the European Union, according to the Financial Times. They are now charging \$23 per dose, up from their previous price of \$18.40, according to the report.

Pfizer and BioNTech also plan to ask the FDA to approve a third dose as a booster shot following full approval. Last week, the Biden administration said it was preparing to offer booster shots to all eligible Americans beginning the week of Sept. 20.

— *CNBC's Rich Mendez contributed to this report.*

