Pfizer-BioNTech vaccine gets full approval

Authorization from FDA could pave way for boosters, mandates

Karen Weintraub and Elizabeth Weise

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Eight months after authorizing the Pfizer-BioNTech COVID-19 vaccine for emergency use in the USA, the Food and Drug Administration issued its full stamp of approval.

Now that the companies' detailed, so-called biologics license application has been granted, it's likely that vaccination will be required by many companies, schools and other entities.

On Monday, President Joe Biden called on companies, nonprofit groups, government agencies and schools to "step up vaccine requirements that will reach millions more people." Vaccinations allowed people in this country to stop worrying about diseases such as smallpox, polio, measles, mumps and rubella, he said, and vaccines can help do the same for COVID-19.

"It only makes sense to require a vaccine to stop the spread of COVID-19," Biden said at a news conference. "With today's FDA full approval, there's another good reason to get vaccinated."

The FDA decision clears the way for the companies to market their vaccine, which is not permitted without full licensure. It may launch a race for booster shots, allowing doctors to prescribe extra Pfizer-BioNTech shots "off label" to anyone they think should get one.

The FDA confirmed late last year through a more streamlined evaluation process that the vaccine, from pharmaceutical giant Pfizer and its partner, German startup BioNTech, was safe, effective and could be reliably produced.

The review of the 340,000-page license application was completed in just 97 days by FDA staff working "night and day," said Dr. Peter Marks, director of the

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FDA's Center for Biologics Evaluation and Research, which approves vaccines.

"We completed this in about 40% of the normal clock time for a submission of this magnitude," he said.

The license application was three times the size of the emergency use authorization submission, which weighed in at 110,000 pages.

able to prescribe it "according to the practice of medicine," also known as off-label.

Marks said last month that full approval would allow for a "broader potential use" of the vaccine, "not that we're recommending off-label uses."

"When we give a biologics license, we are really saying that we have a lot of confidence in that product, in the safety, efficacy, manufacturing information, not just when it's used

be allowed to advertise their vaccine.

The FDA required the companies to continue to study their vaccine to "further assess the risks" of swelling of the heart after vaccination. Since April, more than 1,300 people have reported developing myocarditis or pericarditis after vaccination with either the Pfizer-BioNTech or Moderna vaccine. Most cases were in young men, occurring within a

The companies have manufactured more than 2 billion doses, more than 200 million of which were administered in the USA, the most of any of the three vaccines allowed for use in the country.

The full license includes four more months of efficacy and safety data, confirming trial results and detailing manufacturing processes. The Pfizer-BioNTech emergency use authorization was based on clinical trials involving about 37,000 people. The full approval was based on study results involving more than 44,000 people followed for six months. The license applies only to those 16 and over, but the vaccine is allowed for those 12 to 15 under the previous authorization.

“Based on the longer-term follow-up data that we submitted, today’s approval for those aged 16 and over affirms the efficacy and safety profile of our vaccine at a time when it is urgently needed,” Pfizer chairman and CEO Albert Bourla said in a statement. “I am hopeful this approval will help increase confidence in our vaccine, as vaccination remains the best tool we have to help protect lives and achieve herd immunity.”

Acting FDA Commissioner Janet Woodcock said she hoped the approval would help alter the course of the pandemic in the USA.

“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,” 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.”

exactly according to how it’s labeled, but potentially if it were used somewhat differently by physicians,” he said.

This ability to prescribe off-label means doctors could authorize people to get an extra Pfizer-BioNTech shot, even before booster shots are made available to the general public – likely to be the week of Sept. 20.

“It might discourage people from waiting eight months” to get a booster shot, as the administration recommends, said Dr. Jesse Goodman, an infectious disease specialist at the Georgetown University School of Medicine. It might make it harder for people who are immunocompromised, who are allowed to get boosters now, to access shots, said Norman Baylor, president and CEO of Biologics Consulting. “It could create a competition for the immunocompromised,” he said last week. Otherwise, the change will be mostly psychological, he said in an interview.

“Really, there are not major differences,” said Baylor, who spent 20 years with the FDA, including running its Office of Vaccines Research and Review.

The legal backing of full approval means more businesses and schools will start requiring the COVID-19 vaccine, said Dorit Rubinstein Reiss, a law professor at the University of California, Hastings College of the Law.

Some people reluctant to take a vaccine authorized for emergency use may be willing to get a vaccine that has full approval, presidential medical adviser Anthony Fauci told USA TODAY’s editorial board this month.

few days after vaccination, and they responded well to treatment.

Pfizer-BioNTech agreed to conduct a study to evaluate pregnancy and infant outcomes after vaccination during pregnancy.

Moderna has begun the process of applying for a full license and Johnson & Johnson – which makes the other COVID- 19 vaccine authorized for emergency use in the USA – plans to apply this year.

Vaccine experts reacted positively Monday to the FDA’s approval of Pfizer-BioNTech’s vaccine, called Comirnaty.

“This confirms the safety and incredible effectiveness of this vaccine,” Dr. Richard Besser, president and CEO of the Robert Wood Johnson Foundation and former acting director of the CDC, said in a statement. “I am hopeful that full approval will address any remaining concerns and will move many people to a ‘yes’ on vaccination.”

He said the timing of full approval is crucial as the delta variant of the coronavirus continues to “drive up caseloads and deaths across the U.S.” Delta accounts for virtually all cases. There was an average of 130,000 new infections every day for the past week and more than 700 deaths.

About the full approval

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The full process involves more data and more time in part because once a drug or vaccine is approved by the FDA, doctors are

“I believe that a certain number of people will spontaneously make the decision that ‘OK, now I’m convinced. I’m going to get vaccinated,’” he said.

Full licensure means Pfizer-BioNTech will

