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FDA Gives Full Approval to Pfizer Covid-19 Vaccine

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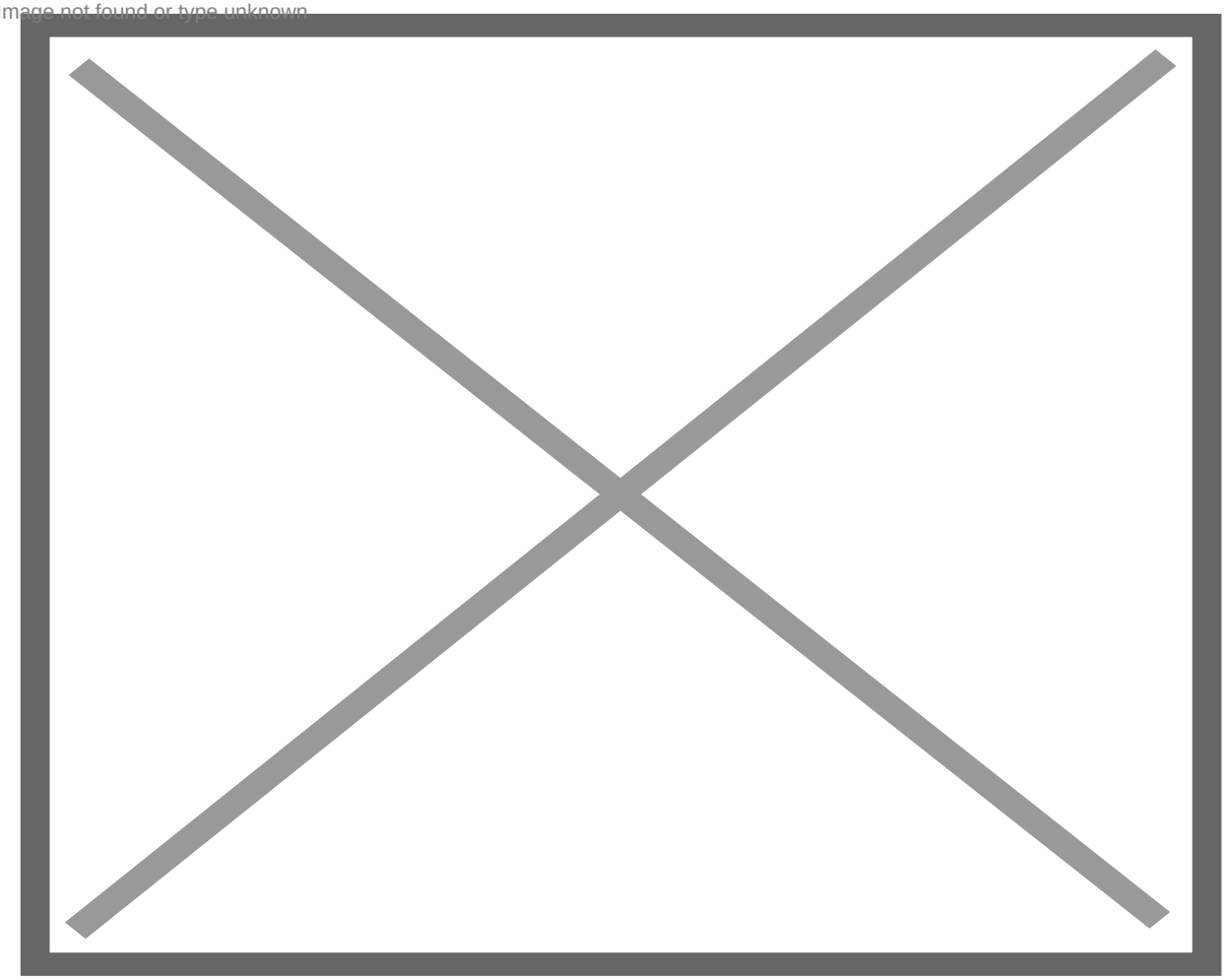

The Food and Drug Administration on Monday approved the Covid-19 vaccine from Pfizer, marking a major milestone in the fight against the coronavirus as well as the push to build confidence in people that the vaccines are safe for use. The FDA's approval gives clearance for people 16 years and older.

The Pfizer drug had received approval in December from the FDA for emergency use after multiple large tests proved the vaccine to be highly effective at preventing illness.

The approval was one of the fastest the FDA has ever cleared, as the federal health authority came under pressure to green light the drug posthaste. The process of approval usually takes 10 months, but the FDA made its decision in less than four months after Pfizer started submitting approval documents.

With full clearance from the FDA secured, Pfizer said it will market the vaccine to the general public, doctors and providers under the name Comirnaty.

“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,” said Pfizer Chief Executive Albert Bourla.

The Pfizer vaccine is also eligible for off-label prescriptions, to include booster doses, the FDA said.

“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,” Peter Marks, director of FDA’s Center for Biologics Evaluation and Research, stated. “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.”

Pfizer said it and partner BioNTech submitted 340,000 pages as part of their approval application. In the data submission were longer-term clinical trial data from more than 46,000 volunteers that showed the vaccine was 91.1 percent effective at preventing symptomatic Covid-19 for up to six months after the second of two doses. FDA's emergency-use authorization in December 2020 was based on data from about 37,000 volunteers who were tracked for a minimum of two months after the second dose.

Additionally, as it prepares to seek full authorization from the FDA for its Covid booster shot, Pfizer said it has already submitted data to the FDA showing that a third dose of its vaccine boosts the immune system against the original virus and against the Beta and Delta variants to higher levels than the standard two-dose regimen, according to the Wall Street Journal.

The FDA's approval will bolster the argument of businesses and institutions that at least the Pfizer vaccine is safe for use as a way to encourage those still skeptical to get inoculated. Some Virgin Islanders have been protesting mandatory vaccine policies instituted by the territory's hospitals as well as the USVI's only institution of higher learning, the University of the Virgin Islands.

Earlier this month, Governor Albert Bryan said all government employees must test weekly for Covid-19 if they are not vaccinated beginning Sept. 9. The governor said the announcement was part of a strategy to make life more difficult for Virgin Islanders who are not inoculated, though the action only affects government employees.

The vaccine from Moderna, which uses similar mRNA technology as Pfizer's, has not been approved as the company is still in the process of submitting data to the FDA. Meanwhile Johnson & Johnson, whose Covid-19 vaccine has seen some setbacks in the U.S., said it planned on seeking full FDA approval later this year.

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