

# Fact check: FDA has fully approved Pfizer's coronavirus vaccine

## The claim: The Food and Drug Administration hasn't fully approved Pfizer's coronavirus vaccine

The Food and Drug Administration [has given its official stamp of approval](#) to Pfizer-BioNTech's coronavirus vaccine. But online, a conspiracy theory doubting that fact has blossomed.

"DECEPTIVE MEDIA: Pfizer-BioNTech COVID-19 Vaccine NOT FULLY AUTHORIZED," reads text in [an Aug. 24 Instagram post](#) from a fan page for Candace Owens, a conservative commentator.

[Similar posts parroting the claim have accumulated thousands of interactions](#) on Facebook and Instagram, according to CrowdTangle, a social media insights tool. The headline comes from [a Substack newsletter](#) published Aug. 24 by Mackenzie Alan Bettle and Hannah Griff.

"To the contrary of what was promulgated by all major media outlets yesterday, the Food & Drug Administration did not grant full approval to the Pfizer-BioNTech COVID-19 vaccine," the conservative writers wrote. "We repeat, the FDA did not grant full approval to any vaccine."

That claim gained traction on 4chan and other anonymous messaging boards before spreading to mainstream platforms, [according to First Draft](#), a nonprofit that tracks online misinformation. The conspiracy theory has also been floated [on a talk show](#) hosted by Steve Bannon – former chief political strategist in the Trump White House – [on conservative websites](#) like the Gateway Pundit and [in Facebook Live videos](#) seen tens of thousands of times.

**Fact check:** [False claim that the FDA was involved in the controversial Tuskegee study](#)

But the claim is bunk. While Pfizer's coronavirus vaccine is still only available to some groups under an emergency use authorization, the FDA has fully approved the shot for most Americans.

USA TODAY reached out to social media users who shared the claim for comment.

## Pfizer vaccine is FDA-approved

The Substack newsletter and related social media posts misconstrue what the FDA wrote in its letter approving Pfizer's coronavirus vaccine.

"The Food & Drug Administration, blatantly admits on page two of its press release, 'On August 23, 2021, having concluded that revising this EUA is appropriate ...'" Bettle and Griff wrote. "Yes, you read that correctly. They are revisiting the Emergency Use Authorization. That means the vaccine still has not been approved for full authorization."

In response to USA TODAY's request from comment, Bettle said Pfizer's vaccine is "not fully authorized because the law says it is not."

"The FDA admits this, too," he said in an email.

It doesn't. The letter Bettel and Griff cite in the newsletter disproves their claim.

Denise Hinton, chief scientist at the FDA, wrote in the Aug. 23 letter that the agency [had "approved the biologics license application"](#) from Pfizer for its coronavirus vaccine "in individuals 16 years of age and older." [In a corresponding press release](#), the FDA said it had fully approved Pfizer's vaccine and that it "will now be marketed as Comirnaty."

That's different from an [emergency use authorization](#).

In December, the FDA [authorized Pfizer's coronavirus vaccine](#) for emergency use. That enabled Americans to get the unapproved shot because, in the context of the coronavirus pandemic, its benefits outweighed its risks. The FDA's decision was based on [data from clinical trials](#) involving tens of thousands of participants, which found the vaccine was safe and effective at preventing symptomatic COVID-19.

In early May, Pfizer [applied for full authorization](#) of its coronavirus vaccine. Three months later, [the FDA approved](#) the company's 340,000-page application, which included additional safety and efficacy data confirming the vaccine's clinical trial results.

The newsletter and related social media posts appear to erroneously conflate two different ways the FDA is regulating Pfizer's coronavirus vaccine.

**Fact check:** [Post about COVID-19 vaccine mandates from government, vaccine companies is partly false](#)

[In its Aug. 23 press release](#), the FDA noted that the vaccine has not been fully approved for all groups. Children ages 12 to 15, as well as immunocompromised individuals seeking a third dose, may receive the vaccine under an emergency use authorization. Children under 12 years old [are not eligible for the shot at all](#).

Still, claims that Pfizer's vaccine is not fully approved for the majority of Americans are wrong.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic," Dr. Janet Woodcock, acting commissioner of the FDA, said in [the Aug. 23 statement](#). "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."

## Our rating: False

Based on our research, we rate FALSE the claim that the FDA hasn't fully approved Pfizer's coronavirus vaccine. The FDA approved Pfizer's application for full authorization Aug. 23. Children ages 12 to 15, as well as immunocompromised individuals seeking a third dose, may still receive the vaccine under an emergency use authorization. But for the majority of Americans, Pfizer's shot is FDA-approved.

## Our fact-check sources:

- USA TODAY, Aug. 23, [Pfizer-BioNTech COVID-19 vaccine becomes first to win FDA's full approval, paving way for boosters, mandates](#)
- CrowdTangle, accessed Aug. 25

- Taboo Talks with Mackenzie Bettle, Aug. 24, [DECEPTIVE MEDIA: Pfizer-BioNTech COVID-19 Vaccine NOT FULLY AUTHORIZED](#) (archived)
- [First Draft Daily Briefing](#), Aug. 25
- U.S. Food and Drug Administration, Aug. 23, [FDA Approves First COVID-19 Vaccine](#)
- U.S. Food and Drug Administration, Aug. 23, [Pfizer-BioNTech COVID-19 Vaccine EUA LOA reissued August 23 2021](#)
- U.S. Food and Drug Administration, Jan. 27, [Biologics License Applications \(BLA\) Process \(CBER\)](#)
- U.S. Food and Drug Administration, Nov. 20, 2020//, [Emergency Use Authorization for Vaccines Explained](#)
- USA TODAY, May 7, [Pfizer-BioNTech seeks full FDA approval for COVID-19 vaccine](#)
- U.S. Food and Drug Administration, Dec. 11, 2020, [FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine](#)
- USA TODAY, Aug. 25, [COVID-19 vaccines for children under 12: When are they coming?](#)
- [Alison Hunt](#), Aug. 26, Email exchange with USA TODAY
- Mackenzie Bettle, Aug. 26, Email exchange with USA TODAY

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*Our fact-check work is supported in part by a grant from Facebook.*