

What is the Difference between FDA Full Approval and Emergency Use Authorization of the Pfizer COVID-19 Vaccine

Recently, Pfizer's COVID-19 vaccine received FDA full approval. With the vaccine now advancing past Emergency Use Authorization, here is what you need to know.

	Emergency Use Authorization	FDA Full Approval
Use is permitted during a declared emergency, such as the COVID-19 pandemic	✓	✓
Use is permitted even when there is no public health emergency		✓
Physicians can prescribe the vaccine “off-label,” for specific purposes (although such use is generally not recommended at this time)		✓
Requires extensive testing through Phase 1, Phase 2, and Phase 3 clinical trials	✓	✓
Testing and production occur at the same time, followed by approval and distribution	✓	
Testing happens before authorization, followed by production and distribution		✓
The manufacturer can market the product to healthcare providers and the public, subject to applicable laws and regulations		✓
Vaccine mandates are possible in states where laws prohibit mandating vaccines authorized only for emergency use		✓
Ongoing monitoring to continue to assure safety and efficacy	✓	✓

For full approval of a new drug, the FDA requires extensive data on safety and effectiveness, inspection of manufacturing facilities, and a comprehensive review of all clinical and “real-world” use. Emergency Use Authorization approval goes through the same safety checks FDA approval requires, however just in a much quicker process.



This product was supported by CDC cooperative agreement U48DP006389. The contents do not necessarily represent the official views of CDC/HHS.