What's the Difference Between Full FDA Approval and Emergency Use Authorization for COVID-19 Vaccines?

Vaccines that are granted an FDA follow the same steps as those that seek EUA approval. However, they can be sent out to people who need them much faster because the vaccines can be made in bulk at the same time as they're being tested.

FDA Approval

Getting a vaccine approved by the FDA takes a few steps. It starts in the lab, moves to animal studies, and then goes to human trials.

PHASE 1   PHASE 2   PHASE 3

Human trials occur in 3 phases. Each phase tests how well these vaccines work and how safe they are for different types of people.

Vaccine makers collect data for months, then apply for FDA approval. If the data meets the high FDA standards, then the vaccine is approved.

The vaccine can then be made in bulk and sent out to the people who need it.

Even after FDA or EUA or approval, the CDC, vaccine makers, and the FDA keep an eye out for safety issues for several months or even years.

For full approval, the FDA wanted to see **six months**' worth of safety data.

VS

Emergency Use Authorization

An EUA uses the same vaccine research and testing steps as FDA approval. The difference is that it lets vaccine makers mass produce vaccines a little bit sooner in the process.

PHASE 1

PHASE 2

PHASE 3

In an EUA, some of the 3 trial phases happen at the same time.

Vaccine makers who want an EUA can start making vaccines during the trial phases. They don't have to wait for the paperwork to clear.

If the FDA finds them to be safe and effective, then the vaccines can get to people faster than they can with approval.

For EUA of the COVID-19 vaccines, the FDA asked for at least **two months** of safety data.

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