

FDA Does Bait and Switch with Moderna's COVID Vaccine, Fully Approves 'SPIKEVAX'



The Food and Drug Administration (FDA) on Monday granted full approval of Moderna's COVID-19 vaccine – except the vaccine it approved currently does not exist and will not be distributed to anyone in the U.S. for the foreseeable future. (Yes, we've seen this before.)

The agency [granted full approval](#) to a vaccine called "SPIKEVAX" which it claimed is "interchangeable" but "legally distinct," from the "Moderna COVID-19" vaccine in an effort to shield the biotech giant from liability for potential harms caused by its product.

"Today, the U.S. Food and Drug Administration approved a second COVID-19 vaccine. The vaccine has been known as the Moderna COVID-19 Vaccine; the approved vaccine will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older," the FDA said in a [press release](#) Monday.

The Moderna COVID-19 vaccine will remain under Emergency Use Authorization (EUA), which was reissued on Jan. 7.

Buried in the small print of its [approval letter](#), the FDA said Spikevax and Moderna's COVID vaccine currently licensed under EUA are "legally distinct" products, with "certain differences that do not impact safety or effectiveness."

This was the same disclaimer given when the FDA approved Pfizer's Comirnaty, which has [never seen the light of day](#) in the U.S.

Just like the Pfizer "approval" fiasco, this vaccine [will not be available](#) to anyone for an indefinite and unspecified period of time.

"Although SPIKEVAX (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in certain individuals within the scope of the Moderna COVID-19 Vaccine authorization, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."

What this means is that people will be given a product that they think is fully approved, while actually receiving an experimental vaccine only authorized for emergency use, as SPIKEVAX does not physically exist.

Furthermore, the FDA stated SPIKEVAX has not been approved or tested with the Omicron variant – which currently accounts for 99.9% of COVID infections in the U.S. – thus it was approved based on former mutations that longer exist in circulation. The same applies to the version of Moderna's COVID vaccine that will remain under an EUA that was recently reissued.

Ironically, the FDA recently