Despite Aggressive Mandates, FDA Hasn’t Approved a COVID-19 Vaccine

Even though the U.S. Food and Drug Administration announced today that it has approved a second COVID-19 “vaccine” known as Spikevax by Moderna, there are still currently no fully FDA-approved licensed shots available. All COVID shots remain under federal emergency use authorization, meaning individuals have the “option to accept or refuse” the product.

In today’s letter to Moderna, the FDA states there is no Spikevax available.

Footnote 9 on page 3 states: “The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.”

Also, footnote 11 on page 7 states: “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.”

Spikevax has the same formulation as the EUA Moderna COVID-19 shot and is administered as a primary series of two doses, one month apart.

The FDA played the same shell game last year when it announced it approved the BioNTech injection, Comirnaty.

On Oct. 20, 2021, the FDA sent a follow-up letter regarding the original approval to Pfizer pharmaceutical company that stated, “having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 23, 2021 letter of authorization in its entirety with revisions incorporated to authorize for emergency use the administration of a single booster dose of Comirnaty.”

On page 6 footnote 12 of that letter, the FDA clearly states, “Although Comirnaty (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, *there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA*” (emphasis added).

The FDA did a bait and switch by announcing it approved its “first COVID-19 vaccine” in order to push the “vaccine” mandates and protect the Pfizer pharmaceutical company from legal liability. The Pfizer injection, on the other hand, is still considered experimental under U.S. law.

The CDC stated:

> *Comirnaty products are not orderable at this time. National Drug Codes are listed per FDA SPL [Structured Product Label] document for the BLA [Biologics License Applications] licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the Cominarty branded NDCs and labels:*
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> *Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. At present,*

> *Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.*

The National Institutes of Health also posted the above statement from Pfizer.

There is a legal difference between products approved under authorization of emergency use compared with those the FDA has fully licensed. The FDA issued another letter for the existing Pfizer shots, which confirms they are still under emergency use authorization are not fully approved and has a liability shield. That means people must be told the risks and benefits, and they have the "option to accept or refuse" the product. The federal emergency use authorization law and the FDA, including the FDA Fact Sheet, state unequivocally that each person has the "option to accept or refuse" the shots.

Liberty Counsel founder and Chairman Mat Staver said, "There is currently no fully FDA-approved licensed COVID shot available to the population. Neither Comirnaty nor Spikevax are available. Everything that is available remains under the EUA law. That means that people have the option to accept or refuse the shots." {eoa}

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