PRESS RELEASE: "Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older."[1]

What does *Comirnaty* mean? Does it mean the drug treatment is FDA approved? Licensed? The answer is found in the approval letter:

"You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials."[2]

Searching *Comirnaty* in DuckDuckGo from August 2010 to August 2020 does not provide a single result. Fiercephrama.com defines it as, "Comirnaty. It's a name we'll all know soon. The new brand name for Pfizer and BioNTech's COVID-19 vaccine, Comirnaty mashes up community, immunity, mRNA and COVID... ."[3]

This FDA approval means they approved a *new name* for marketing the Pfizer Covid shot (Comirnaty) and packaging instructions (2.0 mL glass vials, in packages of 25 and 195 vials). The FDA did not approve or license the vaccine itself.

The FDA's new release says:

"The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age."

The key word here is *including*. It does not exclude individuals over the age of 15.

On the authorization document, it specifically references that they are licensed to *produce* the vaccine,[4] but not that the drug itself is FDA approved or licensed.

21 U.S. Code § 360bbb–3a2 says:[5]

"(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section...

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product")."

Approval and *licensing* are different actions. Under an EUA, a product can be *conditionally* licensed, but that does not mean it is approved. A product may also be approved (i.e., EUA) but not licensed. The Pfizer-BioNTech Covid-19 vaccine was ONLY given permission to be manufactured and marketed under the new name Comirnaty in specific packaging. The vaccine's letter of authorization dated August 23, 2021 says:

"This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older."[6]

BOTTOM LINE: THE INVESTIGATIONAL COVID VACCINE TREATMENT WAS NOT APPROVED AND WAS NOT LICENSED. ONLY THE NAME AND PACKAGING WERE APPROVED BY THE FDA. ALL COVID TREATMENTS TO DATE REMAIN EUA ONLY.

[1] "FDA Approves First COVID-19 Vaccine," FDA. August 23, 2021. Website accessed 8/23/21. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

[2] "BLA Approval," FDA letter to BioNTech/Pfizer. August 23, 2021. Website accessed 8/23/21. https://www.fda.gov/media/151710/download

[3] "The Inside Story Behind Pfizer and BioNTech's New Vaccine Brand Name, Comirnaty," Fierce Pharma. December 23, 2020. Website accessed 8/23/21. https://www.fiercepharma.com/marketing/pfizer-biontech-select-comirnaty-as-brand-name-for-covid-19-vaccine

[4] "BLA Approval," FDA letter to BioNTech/Pfizer. August 23, 2021. Website accessed 8/23/21. https://www.fda.gov/media/151710/download

[5] "21 U.S. Code § 360bbb–3 - Authorization for Medical Products for Use in Emergencies," Cornell Law School. Website accessed 8/23/21. https://www.law.cornell.edu/uscode/text/21/360bbb-3

[6] FDA Letter to Pfizer. April 28, 2023. Website accessed 4/28/23. https://www.fda.gov/media/150386/download