Vaccines: Full Approval – where, how?

Saeed A. Qureshi, Ph.D. (principal@pharmacomechanics.com)

How could the FDA recent letter, Letter of Authorization [1], be considered FULL APPROVAL when the document clearly and repeatedly uses the term EUA (Emergency Use Authorization)? The document ends with a statement,

"*This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act*."

Further, the document states that:

"On August 23, 2021, 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 12, 2021 letter of authorization in its entirety with revisions incorporated* ***to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses****, and to* ***authorize*** *use of COMIRNATY (COVID-19 Vaccine, mRNA)* ***under this EUA*** *for certain uses that are not included in the approved BLA."*

"*The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization*."

"*The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders ...*"

" Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

• This product ***has <u>not</u> 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;*

"I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) ***under this EUA*** *when used to provide a two-dose regimen for individuals*."

For all practical purposes, this letter relates to the renaming of the Pfizer-BioNTech product as COMIRNATY. The following statement in the letter clearly explain this situation

"*COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series*."

It is not uncommon that manufacturers of original products relabel their products for marketing or price advantages to sell them as generics. In such cases, regulatory authorities, including the FDA, grant them approval with minimal filing and administrative requirements, and the product approval is directly linked to the original product (safety, efficacy, and quality) data.

A similar situation is happening here, i.e., COMIRNATY is a generic version of the Pfizer-BioNTech vaccine. Therefore, if the original

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product is not approved yet and remains under EUA, how could a generic version be considered approved or fully approved? It cannot be.

The newly named product (COMIRNATY) is a version of the Pfizer-BioNTech vaccine, which is not approved and will go through the standard approval process in due course. Hence it will automatically follow the fate of the Pfizer-BioNTech vaccine.

On the other hand, it is to be noted that one of the conditions for EUA is the lack of availability of alternatives. For example [2]:

"*Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives*."

Therefore, if COMIRNATY vaccine is considered APPROVED or FULLY APPROVED, then authorization of other vaccines would become null and void. As a result, those vaccines have to be withdrawn from the market. However, this does not appear to be the case. Therefore, all vaccines would remain in the EUA status.

In short, it could be argued that the assumption of FULLY APPROVED status is a false interpretation and conclusion. The status of vaccine use remains under EUA and is highly unlikely to be changed soon from EUA to approval because of the lack of scientific/experimental data supporting effectiveness against the virus [3].

[1] Letter of **Authorization** (Reissued), August 23, 2021 (https://www.fda.gov/media/150386/download)

[2] Emergency Use Authorization for Vaccines Explained. https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

[3] The FDA Committee's Review of Pfizer-BioNTech COVID-19 Vaccine: Unscientific, False and Deceitful. https://bioanalyticx.com/the-fda-committees-review-of-pfizer-biontech-covid-19-vaccine-unscientific-false-and-deceitful/

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