National Vaccine Information Center

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August 30, 2021

RADM Denise M. Hinton, Chief Scientist
Food and Drug Administration (FDA)
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
Email: Denise.Hinton@fda.hhs.gov

Re: FDA August 23, 2021 EUA Reissue Letter to Pfizer[1]

Dear RADM Hinton,

Regarding the above referenced letter reissuing Emergency Use Authorization (EUA) status to the Pfizer-BioNTech and issuing EUA status to BioNTech COMIRNATY COVID-19 vaccines, the National Vaccine Information Center (NVIC) requests clarifications on their individual EUA status and the impact of the "interchangeability" of the two vaccines in relation to the FDA's granting of EUA status as a whole.

More specifically, below are our understandings of the above referenced EUA letter issued by the FDA on August 23, 2021. NVIC requests written confirmation and/or correction and clarification of the below items.

- The Pfizer-BioNTech COVID-19 vaccine's EUA status has been extended for use in persons 12 years of age and older;
- EUA status has been granted to the COMIRNATY COVID-19 vaccine for persons 16 years of age and older;
- The COMIRNATY COVID-19 vaccine has also been authorized for use in for use in persons 12-15 years of age for the two-dose series and a third booster dose for immunocompromised and solid organ transplant recipients, due to FDA's determination that these two COVID-19 vaccines have identical formulations and can be used interchangeability. As a result, COMIRNATY will have the same EUA status of Pfizer-BioNTech COVID-19 vaccine for these additional population uses;
- Despite being licensed by the FDA, COMIRNATY has EUA status. Therefore, the "option" to "refuse" the COMIRNATY vaccine (an EUA product) remains, as provided under federal law and regardless of licensure status.[2]

Further, NVIC respectfully asks for clarification on the following statement made by the FDA, "The products are legally distinct with certain differences that do not impact safety or effectiveness."[3] Please provide specifics on how and why these vaccines are "legally distinct" given that the FDA has also stated:

> "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." [4]

Finally, it is disappointing that the FDA failed to hold a public meeting of the Vaccine and Related Biological Products Advisory Committee (VRBPAC) prior to approving the BioNTech COMIRNATY COVID-19 vaccine. Bypassing the meeting prevented Committee members from providing independent oversight and exercising their duty to make recommendations to the FDA based on their review and evaluation of the safety and efficacy data collected and analyzed since the December 10, 2020 VRBPAC meeting, including post-marketing surveillance safety and efficacy data as it relates to circulating COVID-19 variants.

In particular, in FDA's June 2020 Guidance for Industry document, *Development and Licensure of Vaccines to Prevent COVID-19,* the FDA recommended that vaccine manufacturers be required to meet a minimal primary efficacy endpoint of at least 50 percent in preventing severe COVID-19 disease.[5] We assume that FDA would have provided VRBPAC with current efficacy data as it relates to prevention of severe Delta variant associated disease leading to hospitalization and death. Additionally, not holding a meeting also prevented the FDA and VRBPAC from sharing data and FDA analyses with the public and allowing the public to provide testimony as required under the Federal Advisory Committee Act (FACA) governing the meetings of the VRBPAC.[6]

Members of NVIC's board have previously served as consumer representatives on VRBPAC. As such, NVIC understands that the FDA is not obligated to adopt VRBPAC's recommendations. However, we also recognize the importance for FDA to make data and deliberations transparently open to the public to foster trust and confidence in the COVID-19 vaccine development, testing and licensing process.

Therefore, NVIC requests that the FDA make public the FDA briefing document (or its equivalent) and all other data and analyses that the manufacturer and any others would have provided to VRBPAC and the public, had FDA convened a meeting to discuss whether the BLA meets federal standards for safety and effectiveness. This request is being submitted without a FOIA for the following reasons:

- Publishing this data could strengthen trust between the FDA, scientific community and the public, and help to resolve growing tension arising from a lack of transparency related to approving the BLA for COMIRNATY without public input; and
- This information would have been publicly available on the FDA's website, had the FDA convened the VRBPAC meeting.[7]

In closing, NVIC encourages the FDA to be transparent and release data generated since the VRBPAC's December 2020 review of data and provide responses and clarifications requested herein, as doing so could only be seen by the public as a good faith effort to uphold the trust the public has been asked to place in the FDA.

NVIC looks forward to your prompt response and clarifications.

Regards,

Barbara Loe Fisher
Co-founder & President
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[1] Hinton, Denise M. Letter of Authorization (Reissued), In: Comirnaty and Pfizer-BioNTech COVID-19 Vaccine – Regulatory Information. *FDA* Aug. 23, 2021.
[2] Office of the Law Revision Counsel – United States Code. 21 U.S. Code 360bbb-3- Authorization of medical products for the use in emergencies. Accessed Aug. 28, 2021.
[3] Pfizer-BioNTech. FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
FDA Aug. 23, 2021.
[4] Hinton, Denise M. Footnote 8 – Interchangeability of vaccines and vaccine formulation. In: Regulatory Information - Letter of Authorization (reissued). *FDA* Aug. 23, 2021; Pg 2.
[5] U.S. Department of Health and Human Services – Food and Drug Administration (DHHS – FDA). Statistical Considerations. In: Development and Licensure of Vaccines to Prevent COVID-19 – Guidance for Industry. *FDA* June 2020; Pg 14.
[6] Dean, James L. Public Access to Advisory Committee Records. In: Federal Advisory Committee Management. *U.S. General Services Administration* Mar. 14, 2000.
[7] FDA. Advisory Committee Meeting – Vaccine and Related Biological Products Advisory Committee February 26, 2021 Meeting Announcement. Apr. 26, 2021.