February 23, 2022

Elizabeth A. Brehm, Esq
Siri Glimstad
200 Park Avenue
17th Floor
New York, NY 10166

Dear Ms. Brehm,

This is in response to your December 16, 2021 email on behalf of your client, Informed Consent Action Network, regarding the legal distinctions between the Pfizer-BioNTech COVID-19 Vaccine that FDA has authorized for emergency use and the FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and vaccine availability.

The Pfizer-BioNTech COVID-19 Vaccine was authorized for emergency use by FDA on December 10, 2020, pursuant to Emergency Use Authorization (EUA). Comirnaty, which was approved on August 23, 2021, is the proprietary name for the product licensed under the Biologics License Application (BLA).

There are two formulations of the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use for individuals 12 years of age and older, and these same formulations are also approved under the Comirnaty license for individuals 16 years of age and older. When prepared according to their respective instructions for use, Comirnaty and the two EUA formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. The Vaccine Information Fact Sheet for Recipients and Caregivers for individuals 12 years of age and older provides information about both the licensed and authorized vaccine to ensure potential vaccine recipients understand the product that they will be receiving.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for individuals 12 years of age and older. Comirnaty should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors. Notwithstanding the age limitations for use of the different formulations and presentations of the Pfizer-BioNTech COVID-19 Vaccine and Comirnaty, individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: 1) the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age; or 2) Comirnaty or the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older.

The statutory authorities governing BLAs and EUAs are distinct and provide different legal requirements. The vaccine distributed pursuant to the BLA approval is subject to the requirements of a BLA approved under section 351 of the Public Health Service Act, while the EUA vaccine is subject to the requirements of an EUA issued pursuant to section 564 of the FD&C Act. As an example of the distinct legal requirements, products approved under BLAs are required to have the labeling that was approved as part of the BLA, whereas products authorized under the EUA would have the EUA labeling, and there

may also be differences in manufacturing sites for BLA and EUA vaccine. Both the EUA and BLA processes have required the sponsor to identify specific facilities that will manufacture the vaccine.

Please contact the company or the Department of Health and Human Services (HHS) regarding vaccine availability, as they are best positioned to address the distribution and supply of COVID-19 vaccines. FDA does not have oversight of the distribution of vaccines in the United States.

Sincerely,

Lorrie H. Mcneill -S

Digitally signed by Lorrie H. Mcneill -S
Date: 2022.02.23 16:32:59 -05'00'

Lorrie H. McNeill
Director
Office of Communication, Outreach and Development
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