REQUEST FOR WAIVER OF PREGNANCY REGISTRY REPORT

Part V of *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format Draft Guidance for Industry* dated July 2020 requests the Sponsor to file an interim report of an ongoing registry or a final report on a closed pregnancy registry (if applicable) or other study.

Pfizer/BioNTech are providing the justification below as it relates to Part V for the reason that a pregnancy exposure registry or report of another study is not available for BNT162b2). BNT162b2 vaccine received Emergency Use Authorization (EUA 27034; Pfizer-BioNTech COVID-19 Vaccine) on 11 December 2020 for active immunization to prevent COVID-19 in individuals 16 years of age and older. Neither Pfizer nor BioNTech currently maintain a pregnancy exposure registry that evaluates obstetric, neonatal, and/or infant outcomes among women vaccinated during pregnancy to prevent COVID-19.

The Advisory Committee on Immunization Practices (ACIP) states: "Observational data demonstrate that pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, extracorporeal membrane oxygenation, or death, though the absolute risk for these outcomes is low. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preeclampsia, coagulopathy, and preterm birth. Data on the safety of COVID-19 vaccines in pregnant people are limited. No female reproduction or fetal, embryonal, or postnatal development safety concerns were demonstrated in animals that received Pfizer-BioNTech vaccine before or during gestation. *Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or the fetus because the currently authorized COVID-19 vaccines are non-replicating vaccines and cannot cause infection in either the mother or the fetus. No evidence exists of risk to the fetus from vaccinating pregnant women with non-replicating vaccines in general. However, the potential risks of COVID-19 vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people*. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are underway or planned. Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant." [1]

In accordance with 21 CFR 201.58 Pfizer/BioNTech request a waiver for the labeling requirement to provide a pregnancy exposure registry report or other study report.

[1] Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines | CDC. Available at: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Accessed on: March 17, 2021

Document Approval Record

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Signed By:	Date(GMT)	Signing Capacity
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