



**BLA 125742**

**COVID-19 mRNA Vaccine (nucleoside modified)**

**WAIVER REQUEST FOR FDA-DESIGNATED SUFFIX FOR BIOLOGICS**

**MARCH 2020**

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## 1. INTRODUCTION

Reference is made to BLA 125742 for BNT162b2 [Proposed Proprietary Name “COMIRNATY”; Proposed Nonproprietary Name “COVID-19 mRNA Vaccine (nucleoside modified)”. BNT162b2 is a prophylactic vaccine developed by BioNTech and Pfizer to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2 infection. The proposed indication that is the subject of this initial BLA application is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Further reference is made to the draft Guidance for Industry “Nonproprietary Naming of Biological Products: Update (March 2019)”. As outlined in this guidance, the purpose of the suffix is to ensure safe dispensing and optimal pharmacovigilance of biologic products approved under section 351 of the Public Health Service Act (PHS) that do not contain an FDA designated suffix. Further to this the guidance also states that “Vaccines are currently within the scope of the naming convention described in the Naming Guidance. However, *“FDA is reconsidering that approach and is evaluating whether the currently available identification systems associated with the administration of vaccines are sufficiently robust to ensure safe dispensing practices and optimal pharmacovigilance without requiring distinguishable proper names”*. Pfizer believes that an additional suffix for COVID-19 mRNA Vaccine (nucleoside modified) would be burdensome and redundant as the US Department of Health and Human Services (HHS) has existing methods to ensure safe dispensing and optimal pharmacovigilance of vaccines. These methods include existing vaccination record keeping practices and vaccine safety and monitoring systems. Further to this, the addition of a suffix may be redundant and lead to confusion in dispensing and administration of the vaccine.

## 2. EXISTING METHODS TO ENSURE SAFE DISPENSING AND OPTIMAL PHARMACOVIGILANCE OF VACCINES

As noted above there are several methodologies currently used to ensure the safe use of vaccines. These methods ensure robust adverse event reporting, monitoring and tracking of vaccine administration. These methods combined are robust and support the fact that the addition of a suffix would not be necessary for vaccines.

### 2.1. VACCINATION RECORD KEEPING METHODS

Existing vaccination record keeping methods include;

- The National Childhood Vaccine Injury Act which requires Health Care Professionals to provide a vaccine information statement (VIS) to patients/guardians prior to administration as well as to report adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Immunization Information Systems consolidate vaccination histories to help assure timely vaccination scheduling and provides aggregate vaccination data for use in surveillance systems as well as to inform on public health decisions and goals related to vaccines.

## 2.2. VACCINE SAFETY MONITORING SYSTEMS

Vaccine safety monitoring systems include;

- Vaccine Adverse Event Reporting System (VAERS) is designed to detect safety concerns with vaccines. HCPs and manufactures are required to report adverse events to VAERS. Consumers can also report to this system and further reporting may be burdensome and discouraging.
- Vaccine Safety Datalink (VSD) which utilizes data from doctors' offices, urgent care visits, emergency department visits, and hospital stays to monitors vaccine safety and conduct studies on rare and serious side effects of vaccines. These studies also include concerns raised in literature. The VSD also submits their reports to VAERS.
- The Post-Licensure Rapid Immunization Monitoring System (PRISM) is yet another means by which vaccine safety is evaluated. As part of the Agency's Sentinel system, PRISM is linked to statewide registries and is being used to develop signal detection tools for evaluation of adverse events.

## 3. CONCLUSION

As outlined above, there are adequate policies and systems in place to ensure the safe dispensing and optimal pharmacovigilance of vaccines which COVID-19 will be subject to. Additional requirements such as a designated suffix may be redundant and burdensome. Toward that end, we respectfully request a waiver from the requirement for an FDA designated suffix for COVID-19 mRNA Vaccine (nucleoside modified), the subject of this BLA application.

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