Pfizer Global Regulatory Affairs
Pfizer Inc.
400 Arcola Road Collegeville, PA 19426

Global Product Development

18 May 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Re: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Part 2, final, of the Original Submission – Rolling Biologics License Application (BLA)

Dear Dr. Gruber,

Please find enclosed Part 2 of the Original Submission of the rolling Biologics License Application (BLA) for the BNT162b2 vaccine candidate developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age. This vaccine was granted Fast Track Designation for individuals ≥18 years of age on 07 July 2020 (Grant Fast Track Designation Letter).

Part 1 of the rolling BLA, containing the complete non-clinical and clinical contents of the application and Priority Review Designation Request, was submitted on 06 May 2021. FDA acknowledgement of receipt of that submission was received on 13 May 2021, and the submission was assigned tracking number BL 125742. This submission (Part 2 of the rolling submission) completes the Biologics License Application.

The User Fee for this application was paid prior to submission of roll 1 of the BLA (05 May 2021; User Fee ID#PD3017966), and the user fee cover sheet (Form 3397) was submitted with the first submission on 06 May 2021.

The purpose of this submission is to complete the application. This submission is provided in electronic Common Technical Document (eCTD) format. The Table of Contents is attached. As agreed during the teleconference of 16 April 2016, sequencing data requested by the Agency on 09 March 2021 will be provided during the course of review of the BLA by 07 June 2021.

Any reference not included with this submission is available upon request.

A Request for Proprietary Name Review will be submitted separately to this BLA as an amendment following this submission.

On 10 August 2020 it was agreed that BioNTech could be provided their US License Number upon submission of the BLA (as opposed to at approval). We kindly request the US License Number for BioNTech with agreement that they will not use it until after the BLA is approved.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at elisa.harkinstull@pfizer.com.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.

BLA 125742 Part 2 Table of Contents

	MODULE 1
1	**Administrative Information and Prescribing Information**
1.1	**Forms**
	FDA 356h Form: Application Form
1.2	**Cover Letters**
	Cover Letter
1.4	**References**
1.4.2	**Statement of Right to Reference**
	DMF Letters of Authorization
1.12	**Other Correspondence**
1.12.14	**Environmental Analysis**
	Environmental Analysis
1.14	**Labeling**
1.14.1	**Draft Labeling**
1.14.1.1	**Draft Carton and Container Labels**
	Diluent Labeling Proposal
	Fresenius Kabi Diluent Carton (Attachment 1)
	Fresenius Kabi Diluent Stamp (Attachment 2)
	Hospira Diluent Carton (Attachment 3)
	Hospira Diluent Label (Attachment 4)
	Carton COM25CTPUS - Puurs
	Carton COM25CTKZ - Kzoo
	Carton Label COM195LPUS - Puurs
	Carton Label COM195LKZ - Kzoo
	Vial COMVLABP - Puurs
	Vial COMVLABKZ - Kzoo
1.14.1.2	**Annotated Draft Labeling Text**
	Annotated Draft Labeling Text
1.14.1.3	**Draft Labeling Text**
	Draft Labeling Text (Word, PDF, SPL)
1.14.1.5	**Labeling History**
	Summary of Literature Search on Pregnancy, Lactation and Fertility
	Pregnancy and Lactation Cumulative Review
	Waiver Request for Summary of Drug Utilization Rates
	Waiver Request for Pregnancy Registry Report
1.16	**Risk Management Plans**
1.16.1	**Risk Management (Non-REMS)**
	Pharmacovigilance Plan
	COVID-19 Vaccine VAED Data Capture Aid
	COVID-19 Vaccine Anaphylactic Reaction Data Capture Aid
	MODULE 2

2	**CTD SUMMARIES**
2.3	**Quality Overall Summary**
	Quality Overall Summary
	MODULE 3
3	**QUALITY**
3.2	**Body of Data**
3.2.S	**Drug Substance**
3.2.S.1	General Information
3.2.S.2	Manufacture
3.2.S.3	Characterization
3.2.S.4	Control of Drug Substance
3.2.S.5	Reference Standards or Materials
3.2.S.6	Container Closure System
3.2.S.7	Stability
3.2.P	**Drug Product**
3.2.P.1	Description and Composition of the Drug Product
3.2.P.2	Pharmaceutical Development
3.2.P.3	Manufacture
3.2.P.4	Control of Excipients (compendial)
3.2.P.4	Control of Excipients (non-compendial)
3.2.P.5	Control of Drug Product
3.2.P.6	Reference Standards or Materials
3.2.P.7	Container Closure System
3.2.P.8	Stability
3.2.A	**Appendices**
3.2.R	**Regional Information**
3.3	**Literature References**
	MODULE 5
5	**CLINICAL STUDY REPORTS**
5.3	**Clinical Study Reports**
5.3.5	**Reports of Efficacy and Safety Studies**
5.3.5.1	**Reports of Controlled Clinical Studies Pertinent to the Claimed Indication**
	C4591007 Protocol - A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children <12 Years of Age
	C4591015 Protocol - A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of A SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older
5.3.5.4	**Other Clinical Study Reports**
	C4591008 Protocol - HERO Together: A Post-Emergency Use Authorization Observational Cohort Study to Evaluate the Safety of the Pfizer-BioNTech COVID-19 Vaccine in US Healthcare Workers
	C4591009 Protocol Synopsis - A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States

	C4591011 Protocol - Active Safety Surveillance of the Pfizer-BioNTech COVID-19 Vaccine in the United States Department of Defense Population Following Emergency Use Authorization
	C4591012 Protocol - Post-Emergency Use Authorization Active Surveillance Study among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine
	C4591014 Protocol - Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California
	C4591022 Protocol Synopsis - A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry
	WI235284 Protocol - Determining RSV Burden and Outcomes in Pregnant Women and Older Adults Requiring Hospitalization
	WI255886 Protocol - Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-pandemic Acute Lower Respiratory Tract Disease Surveillance Study
5.4	**Literature References**