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

Global Product Development

17 June 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)

Response to 9 June 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) 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. Further reference is made to the request for *Pediatric Research Equity Act* (PREA) milestone dates for studies C4591001 and C4591007 sent via email from Captain Michael Smith on 9 June 2021. The requested PREA milestone dates are provided below.

Study C4591001: Ages 12 Through 17 Years
Final Protocol Submission: 22 April 2020
Study Completion: 31 May 2023
Final Report Submission: 31 October 2023

Study C4591007: 11 years of age and younger
Final Protocol Submission: 18 December 2020
Study Completion: 31 August 2023
Final Report Submission: 29 February 2024

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.