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

Global Product Development

15 July 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 FDA 13 July 2021 Information Request Regarding Preservative Exception or Alternative Submittal

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 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.

On 13 July 2021, the Agency requested via email that BioNTech and Pfizer submit a request and a justification for an exception or alternative to the requirement under 21 CFR 610.15(a) that products in multiple-dose vials include a preservative because the candidate vaccine is supplied in a multiple-dose vial that does not contain a preservative. Response to the Agency's Information Request is provided in Module 1.11.1 (Response to 13 July 2021 FDA IR). The Request for Exception to the 21 CFR 610.15(a) Requirement for a Preservative is provided in Module 1.12.5.

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.
CC: Captain Michael Smith, Ph.D.
CC: Laura Gottschalk, Ph.D.