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

Global Product Development

20 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's 16 July 2021 Information Request Regarding a Templated Lot Release Protocol (LRP) Template and for Additional Sample Handling Information

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 25 June 2021, the Agency sent an Information Request regarding for the lot release protocol (LRP) template and for samples and reagents. The requested information was provided on 09 July 2021. An additional request was made on 16 July 2021 to include a templated lot release protocol as well as instructions for thawing and number of acceptable freeze-thaw cycles. This information is provided in Response to 16 July 2021 FDA IR in Module 1.11.1.

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