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

# Global Product Development

16 August 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 August 2021 Information Request Regarding Test Methods, the lot release process, and Lot Release Protocol (LRP) Template**

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 August 2021, the Agency sent an Information Request regarding Test Methods, the lot release process, and LRP template. The requested information is provided in Response to FDA 13 August 2021 Information Request is provided in Module 1.11.1.

The LRP template was submitted via email for review on 14 August 2021 by Mr. Paul Rohlfing, Pfizer Inc. and agreed upon by Captain Michael Smith (CBER) via email on 14 August 2021. The LRP provided in this response is identical to that provided via email.

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.