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

# Global Product Development

19 July 2021

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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)**

**General Correspondence**

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 Agency's Filing Notification for BLA 125742 dated 15 July 2021 sent via email from Dr. Laura Gottshalk, CBER, OVRR to Ms. Elisa Harkins, Pfizer Inc. on 16 July 2021.

I am writing on behalf of Pfizer and BioNTech to waive our rights to the mid- and late-cycle review meetings for BLA 125742.

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.



FDA-CBER-2021-5683-0780571