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

Global Product Development

19 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 125742.0

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Response to FDA 18 August 2021 Information Request: DBSQC Comments

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 18 August 2021, the Agency sent an Information Request regarding the recent submission on August 16th (Commitment to FDA 13 August 2021 Information Request Regarding Implementing New Method for Endotoxin) and August 17th (Response to FDA 13 August 2021 IR regarding test methods, the lot release process, and the lot release protocol template). On 17 August 2021, the Agency and Pfizer met via teleconference to obtain clarity on the given request. The Response to 18 August 2021 Information Request: DBSQC Comments is provided 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.