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

Global Product Development

19 May 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)

REQUEST FOR PROPRIETARY NAME REVIEW

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.

The purpose of the present submission is to provide the Request for Proprietary Name Review in Module 1.18. As detailed in the 2016 FDA *Guidance for Industry - Contents of a Complete Submission for the Evaluation of Proprietary Names*, this Request for Proprietary Name Review is being submitted as a separate submission to the BLA. This request was previously reviewed under BB-IND 19736 and the Acceptable At This Time Letter was received from FDA on 20 November 2020. Please note, this is the same proprietary name that has been accepted and is currently in use globally for all regions who have Conditional Marketing Authorization for this vaccine, including the European Union.

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.