Pfizer Global Regulatory Affairs
Pfizer Inc
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Global Product Development

17 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)

CMC Amendment Regarding 9-Month Shelf Life Extension for the Undiluted Drug Product at -90 to -60 °C

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.

This amendment to BLA 125742 contains the same supporting data submitted to EUA 27034 Amendment 260 on 13 August 2021, to support a shelf-life extension of the undiluted drug product of up to 9-months when stored at the intended long term storage condition. Due to the differences between the leaflet structure of the IND and the BLA, formatting of the submissions is slightly different. A summary of changes is supporting these updates is provided below:

- Introduction of additional stability data to support extending the shelf-life of the undiluted drug product vial from 6 months to 9 months when stored at -90 to -60 °C.
- Corrections made a typographical error in DSPC result for lot EJ0553 made in a stability data tables that occurred in a previous submission.
- Addition of inverted vial orientation data for various lots at the 5° C and -20° C long term and accelerated conditions.

- Addition of Figures illustrating stability data for LNP polydispersity, LNP size, RNA content, RNA encapsulation, lipid content, RNA integrity, and in vitro expression.

A Module 2, 2.3 Introduction is included and contains a comprehensive list of new or revised documents to provide CBER with a comprehensive CMC package for review.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

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