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

Global Product Development

13 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 09 August 2021 Information Request Regarding Draft COMIRNATY Vial and Carton Labels

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.

The purpose of this submission is to respond to CBER's 09 August 2021 request for additional information and updates regarding the proposed COMIRNATY Draft Vial and Draft Carton Labels, received via email from Captain Michael Smith, PhD (CBER). The updated Vial Labels, Carton Labels and Diluent Sticker are provided in Module 1.14.1:

- Carton Label (195-Pack) for Puurs; Carton Label (195-Pack) for Kalamazoo
- Carton Label (25-Pack) for Puurs; Carton Label (25-Pack) for Kalamazoo
- Diluent Sticker
- Vial Label for Puurs; Vial Label for Kalamazoo

Additionally, reference is also made specifically to CBER's comment 5, Pfizer/BioNTech can confirm, as previously agreed with CBER that serialization would not be a requirement on the carton for the duration of the global pandemic.

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.