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

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)

Response to FDA 16 August 2021 Information Request Regarding Carton and Container 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 16 August 2021 information request regarding the packaging labels received via email from Captain Michael Smith, Ph.D. (CBER). Response to FDA 16 August 2021 Information Request is provided in Module 1.11.3. Updated packaging labels to accompany the response are provided in Module 1.14.1:

- COMIRNATY Carton Label (195-Pack) for Puurs; COMIRNATY Carton Label (195-Pack) for Kalamazoo
- COMIRNATY Carton Label (25-Pack) for Puurs; COMIRNATY Carton Label (25-Pack) for Kalamazoo
- Diluent Vial Label for Hospira; Diluent Carton Label for Hospira
- Diluent Vial Label for Fresenius Kabi; Diluent Carton Label for Fresenius Kabi

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.
Captain Michael Smith, Ph.D.
Laura Gottshalk, Ph.D.