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

Global Product Development

24 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)

Response to FDA 20 May 2021 Information Request Regarding Manufacturing Schedules for the Pfizer Andover, Puurs and Kalamazoo Manufacturing Facilities and COVID-19 Precautions at Each Manufacturing Facility

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 20 May 2021, the Agency provided an Information Request regarding manufacturing schedules for the Pfizer Andover, Puurs, and Kalamazoo manufacturing facilities as well as COVID-19 precautions taken at each manufacturing facility related to visitor entry requirements. The requested information is provided in Response to 20 May 2021 FDA IR in Module 1.11.1.

Additional requirements for travel to Belgium are provided in:

- Guidelines for Business Travel from a Red Zone to Belgium in Module 3.2.R
- Requirements for Travel to Belgium in Module 3.2.R

In addition, the Agency requested a teleconference to discuss production schedules and (b) (4) for the Puurs, Belgium site. A teleconference has been scheduled and confirmed for Tuesday, 25 May 2021 starting at 10:00 AM ET.

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.