



Global Product Development

20 August 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
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Re: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Change in Sponsor Authorized Representative for BLA 125742 (and Revised 1.4.3 List of Authorized Persons)

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.

I am writing to inform you of a change in the Sponsor Authorized Representative for BLA 125742. Effective 23 August 2021, Neda Aghajani Memar, Pharm.D. will be replaced by Amit Patel, Director, Global Regulatory Affairs – Vaccines. Amit Patel's contact information is provided below.

Amit Patel
Director, Global Regulatory Affairs – Vaccines
Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Mobile Phone: 214-918-5262
Email: Amitkumar.Patel@pfizer.com

The revised [1.4.3 List of Authorized Persons](#) is provided in this submission.

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.