



Global Product Development

17 September 2021

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Office of Vaccines Research and Review
Food and Drug Administration
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Re: COVID-19 Vaccine (BNT162/PF-07302048) BLA 125742/10

BLA Amendment – Change in Sponsor Authorized Representatives for BLA 125742 (and Revised 1.4.3 List of Authorized Persons)

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) 125742 for COMIRNATY (COVID-19 mRNA Vaccine), developed by BioNTech and Pfizer for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age issued on 23 August 2021.

I am writing to inform you of the addition of two Sponsor Authorized Representatives for BLA 12572, effective on 17 September 2021. Adrienne Stafford, Director, Global Regulatory Affairs, CMC, Pfizer Vaccines and Rich Pelt, Sr. Director, Global Regulatory Affairs, CMC, Pfizer Vaccines are being added as sponsor authorized representatives. The previously provided sponsor authorized representatives remain valid.

Adrienne Stafford
Director, GCMC Vaccines
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Rich Pelt
Senior Director, GCMC Vaccines
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The [Revised List of Authorized Persons](#) is also provided in this submission in module 1.4.3.

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 214-918-5262 or via e-mail at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs - Vaccines

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.
CC: Captain Michael Smith, Ph.D.