



Global Product Development

28 July 2021

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Director
Office of Vaccines Research and Review
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Re: BLA 125742

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

Response to FDA's 02 July 2021 Information Request Regarding CMC Information and Categorical Exclusion for an Environmental Analysis.

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 02 July 2021, the Agency sent an Information Request regarding CMC information and categorical exclusion for an environmental analysis. The requested information is provided in [Response to 02 July 2021 FDA IR](#) in Module 1.11.1.

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.
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