



Global Product Development

11 August 2021

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Re: BLA 125742

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

Response to FDA's 04 August 2021 Information Request Regarding the Lot Release Protocol Template

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 04 August 2021, the Agency sent an Information Request regarding the lot release protocol template. The requested information is provided in [Response to 04 Aug 2021 FDA Information Request – Lot Release Protocol \(LRP\) Template](#) in Module 1.11.1.

A number of questions are included in this response. Pfizer/BioNTech respectfully request feedback not later than 18 August 2021.

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.
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