



## Global Product Development

13 August 2021

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**Re: BLA 125742**

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

**Response to FDA 06 August 2021 Information Request Regarding Measurement of Endotoxins**

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  $\geq 16$  years of age.

On 06 August 2021, the Agency sent an Information Request regarding the measurement of endotoxins using the (b) (4) LAL procedures. The requested information is provided in [Response to 06 August 2021 FDA Query on the Measurement of Endotoxins](#) 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](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

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