



## Global Product Development

17 August 2021

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**Re: BLA 125742.0**

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

**Commitment to FDA's 13 August 2021 Information Request Regarding  
Implementing New Method for Endotoxin**

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 13 August 2021, the Agency sent an Information Request for a new method for testing (b) (4) samples. In addition, on 16 August 2021, the Agency and Pfizer met via teleconference to obtain clarity on the given request. The requested information and commitment are provided in [Commitment to Implement an Additional Endotoxin Method on \(b\) \(4\) DP](#) 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  
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Global Regulatory Affairs – Vaccines

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