**Pfizer Global Regulatory Affairs** Pfizer Inc. 400 Arcola Road Collegeville, PA 19426



## **Global Product Development**

15 July 2021

Marion Gruber, Ph.D. Director Office of Vaccines Research and Review Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue WO71, G112 Silver Spring, MD 20993-0002 THIS DOCUMENT CONTAINS CONFIDENTIAL AND/OR TRADE SECRET INFORMATION THAT IS DISCLOSED ONLY IN CONNECTION WITH THE LICENSING AND/OR REGISTRATION OF PRODUCTS FOR PFIZER INC OR ITS AFFILIATED COMPANIES. THIS DOCUMENT SHOULD NOT BE DISCLOSED OR USED, IN WHOLE OR IN PART, FOR ANY OTHER PURPOSE WITHOUT THE PRIOR WRITTEN CONSENT OF PFIZER INC.

## Re: BLA 125742

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

## **Response to FDA 13 July 2021 Information Request Regarding Preservative Exception or Alternative Submittal**

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 July 2021, the Agency requested via email that BioNTech and Pfizer submit a request and a justification for an exception or alternative to the requirement under 21 CFR 610.15(a) that products in multiple-dose vials include a preservative because the candidate vaccine is supplied in a multiple-dose vial that does not contain a preservative. Response to the Agency's Information Request is provided in Module 1.11.1 (Response to 13 July 2021 FDA IR). The Request for Exception to the 21 CFR 610.15(a) Requirement for a Preservative is provided in Module 1.12.5.

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.

Marion Gruber, Ph.D., Director BLA 125742

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Sincerely,

Elisa Harkins Global Regulatory Lead Global Regulatory Affairs – Vaccines

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

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