



Global Product Development

06 July 2021

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SN 0397

Re: Covid-19 Vaccine (BNT162/PF-07302048) BB-IND 19736

Response to FDA 30 June 2021 Information Request

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for the COVID-19 vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The IND was effective on 29 April 2020.

Further reference is made to CBER's 30 June 2021 Information Request regarding updating Informed Consent Documents and Investigator's Brochure with information related to myocarditis and pericarditis.

The present submission provides [Response to FDA 30 June 2021 Information Request](#) in Module 1.11.3.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Marion Gruber, Ph.D., Director
BB-IND 19736

Page 2 of 2
06 July 2021

Neda Aghajani Memar, Pharm.D.
Director
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CC: Ramachandra S. Naik, Ph.D.
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