



Global Product Development

19 May 2021

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Re: BLA 125742

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

Response to 18 May 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 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.

Reference is made to Amendment 132 (dated 09 April 2021) to EUA 27034 to extend emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine to individuals 12-15 years of age. Further reference is made to the teleconference held on 08 April 2021 and Roll 1 of BLA STN 125742/0 (dated 06 May 2021). The purpose of the current document is to respond to CBER's 18 May 2021 Information Request regarding datasets that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email.

The purpose of the present submission provides the [Response to CBER's 18May2021 Information Request](#) in Module 1.11.3.

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.