



## Global Product Development

03 August 2021

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SN 0433

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

**Request for Comments and Advice – Adolescent (12-15 Years of Age)  
Supplemental BLA Proposal**

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.

Reference is also made to the Biologics License Application (BLA) 125742 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  $\geq 16$  years of age.

The present submission provides a [Request for Comments and Advice](#) (Module 1.12.4) regarding a proposal to submit a supplemental Biologics License Application (sBLA) to extend the age group to include adolescents 12 through 15 years of age.

Pfizer/BioNTech respectfully request feedback from the Agency regarding the acceptability of our proposed datasets to support a sBLA no later than 17 August 2021.

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](mailto:neda.aghajanimemar@pfizer.com).

Sincerely,

Neda Aghajani Memar, Pharm.D.  
Director  
Pfizer Global Regulatory Affairs

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CC: Captain Michael Smith, Ph.D.