



## Global Product Development

19 August 2021

Marion Gruber, Ph.D.  
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**Re: BLA 125742**

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

### **Response to FDA 18 August 2021 Information Request Regarding Inclusion of Draft Carton and Container Labels in a Single Amendment**

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.

Reference is made to CBER's 18 August 2021 request to submit, in a single amendment, all of the draft labels listed in the below amendments. The present submission addresses CBER's request.

- Amendment 46 (Seq 0046, dated 08/13/2021)
  - [COMIRNATY Vial Label \(Kalamazoo\)](#)
  - [COMIRNATY Vial Label \(Puurs\)](#)
  - [Diluent Sticker \(Hospira\)](#)
  
- Amendment 53 (Seq 0054, dated 08/17/2021)
  - [COMIRNATY Carton – 25 Vial \(Kalamazoo\)](#)
  - [COMIRNATY Carton – 25 Vial \(Puurs\)](#)
  - [COMIRNATY Carton – 195 Vial \(Kalamazoo\)](#)

- COMIRNATY Carton – 195 Vial (Puurs)
  - Diluent Vial (Fresenius Kabi)
  - Diluent Vial (Hospira)
  - Diluent Carton – 25 Vial (Fresenius Kabi)
  - Diluent Carton – 25 Vial (Hospira)
- As agreed by the Agency via email from Laura Goddshalk, PhD, FDA, CBER, OVRP to Elisa Harkins, Pfizer Inc. via email on 19 August 2021 the Diluent Stamp for Fresenius Kabi will not be provided because Fresenius Kabi would need to stop their packaging operations for this, which is not feasible in the timeframe request by CBER for this response.. The stamp will be updated in alignment with the text included in the Diluent Sticker for Hospira (provided in this submission).

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  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

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