



**BNT162b2 (COMIRNATY)**

**BLA STN 125742/0**

**Response to CBER 18 August 2021 Information Request Regarding  
Identification of BLA Compliant Lots and Dear HCP Letter**

**19 August 2021**

090177e197da0346\Approved\Approved On: 19-Aug-2021 13:11 (GMT)

## 1. INTRODUCTION

Reference is made to BLA STN 125742/0 for COVID-19 mRNA Vaccine (COMIRNATY), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals  $\geq 16$  years of age and to CBER's Information Request received via email on 18 August 2021.

CBER requests are presented in *bold italics* followed by Pfizer-BioNTech response in plain text.

## 2. CBER REQUEST AND SPONSOR RESPONSE

*Reference is made your [Donna Boyce, Senior Vice President, Head of Global Regulatory Affairs, Pfizer Inc.] August 16, 2021 email communication and telephone conversation with Mary Malarkey, Director, OCBQ/FDA, in which you shared a graphic for identification of BLA-compliant lots and draft Dear HCP Letter. Please submit these and any relevant documents as an amendment to the BLA.*

*If these documents have already been submitted, please point us to the amendment/sequence number and when these were submitted.*

### Sponsor Response

The graphic, [Identification of BLA-Compliant Lots](#), and the [Dear HCP Letter-COMIRNATY Lots](#) are attached. Please note, the version of the Dear HCP Letter attached here is different from the version emailed to Mary Malarkey because this is the final draft version that is intended to be used upon approval of COMIRNATY. Please also note, "BLA-complaint" as cited in the graphic is a typographical error.

## Document Approval Record

**Document Name:**

Response to FDA 18-Aug-2021 IR Identification of BLA-compliant Lots and Letter to HCP

**Document Title:**

Response to FDA 18-Aug-2021 IR Identification of BLA-compliant Lots and Letter to HCP

**Signed By:**

**Date(GMT)**

**Signing Capacity**

Harkins Tull, Elisa

19-Aug-2021 13:11:55

Regulatory Affairs Approval

090177e197da0346\Approved\Approved On: 19-Aug-2021 13:11 (GMT)