



BNT162b2 (COMIRNATY)

BLA STN 125742/0

**Response to 20 August CBER Information Request Regarding Label for Identification
of BLA Lots and Dear HCP Letter**

20 August 2021

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LIST OF ABBREVIATIONS

Abbreviation	Term
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
COVID-19	coronavirus disease 2019
FDA	United States Food and Drug Administration
HCP	Health Care Provider
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2

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1. INTRODUCTION

Reference is made to BLA STN 125742/0 for the Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age.

The purpose of this document is to respond to CBER's Information Request communicated from Ramachandra Naik, PhD (CBER) to Elisa Harkins Tull (Pfizer Inc.) via email on 20 August 2021, requesting information the label for identification of BLA lots and the Dear HCP letter.

CBER's comments/requests in ***bold italics*** are followed by the Sponsor's responses below.

2. CBER REQUESTS

2.1. CBER Request 1

Our review of the information provided in your BLA STN 125742 for COMIRNATY (COVID-19 mRNA Vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. Please see the attached for CBER's comments and revisions regarding the information included in amendment 64 (dated August 19, 2021) about the label to include with the vaccine tray package and the draft Dear HCP Letter.

Please refer to our August 20, 2021, 2:08 PM email communication regarding lots that you consider to be BLA-compliant, and confirm that EUA-labeled "lots in the field" will not be listed at [cvdvaccine-us.com/resources](https://www.cvdvaccine-us.com/resources) until they are released by CBER.

Please provide your response in an Amendment to STN 125742/0, as soon as possible.

Response

Pfizer/BioNTech has updated the Dear HCP Letter and the graphic regarding identification of the BLA lots. The revised [Dear HCP Letter- COMIRNATY Lots](#) and [Graphic – Recommendation – Identification of BLA Lots](#) graphic are attached.

Pfizer/BioNTech confirms that EUA-labeled "lots in the field" will not be listed on [cvdvaccine-us.com/resources](https://www.cvdvaccine-us.com/resources) until they are released by CBER.

Document Approval Record

Document Name: August 2021 COVID-19 Response to 20Aug2021 CBER Request- label ID of BLA lots and Dear HCP Letter

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Signed By:	Date(GMT)	Signing Capacity
Harkins Tull, Elisa	20-Aug-2021 21:19:59	Regulatory Affairs Approval