

August 23, 2021

RE: Pfizer-BioNTech COVID-19 Vaccine Now FDA Approved as COMIRNATY® IMPORTANT PRODUCT INFORMATION

Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

Dear Healthcare Professional,

Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at covidvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,



Donna Boyce

Senior Vice President, Global Regulatory Affairs

BIONTECH

COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

[US License No. 2229](#)





FDA-CBER-2021-5683-0951270
2021TA035 v1.0

If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...



Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

WHAT?

If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy the letter with QR code in each of the smaller, portable packaging containers being used for transport.

WHY?

Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved.

HOW?

To create additional copies of the letter to include in smaller transport containers, you may:

- Make a copies) of this letter using a copy machine
- Make printouts by visiting covidvaccine-us.com/resources

For questions related to this notification please contact Pfizer Customer Service at 1-800-666-7248.



Document Approval Record

Document Name: 20 August 2021 for CBER- Attachment Dear HCP Letter_COMIRNATY Lots

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Signed By:	Date(GMT)	Signing Capacity
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