

August XX, 2021



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

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

Manufactured by Pfizer Inc. New York, NY 11017

USL license No. 2229

**Specified Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the approved specifications in Biologics Licensing 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 (now FDA approved as COMIRNATY®).

The Pfizer-BioNTech COVID-19 Vaccine (also known as COMIRNATY®) was licensed for use on August XX, 2021. Generally, when a product is licensed, the product's brand name, in this case, COMIRNATY®, is used from that point on.

Several lots of the vaccine are in circulation that were approved for Emergency Use Authorization and labeled as "Pfizer-BioNTech COVID-19 Vaccine". **These lots comply with the specifications required in the recently approved Biologics License Application 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 [cvdvaccine-us.com/resources](http://cvdvaccine-us.com/resources)

**Please note, it is imperative that you not discard any available EUA lots. You should continue to maintain and use them up to the date of expiry.**

Please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. The information can be found by scanning the QR code.

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

Sincerely,



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

**WHAT?**

If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy of this letter 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 this letter to include in smaller transport containers, you may:

- Make a copies) of this letter using a copy machine
- Make printouts by visiting [cvdvaccine-us.com/resources](http://cvdvaccine-us.com/resources)

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