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 regarding the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use under a Limited Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 17696. The Pfizer-BioNTech COVID-19 Vaccine is in circulation that were authorized for emergency use and are labelled in accordance with the EUA. Some of these lots continue to be BLA for COMIRNATY and are therefore considered “BLA-approved”. The lots that are BLA-approved may be found at cdvaccine-us.com/resources. For these lots, please refer to the full prescribing information for indication and usage, dosing and administration, and safety information. This information can be found by scanning the barcode on the label. It is imperative that you not discard any available EUA lots. These lots are authorized for use under EUA in individuals 12 years of age and older, and for immunocompromised individuals. You can continue to use these lots until the new formulation is ready.

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

Pfizer

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