

August 23, 2021

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

PRODUCT INFORMATION

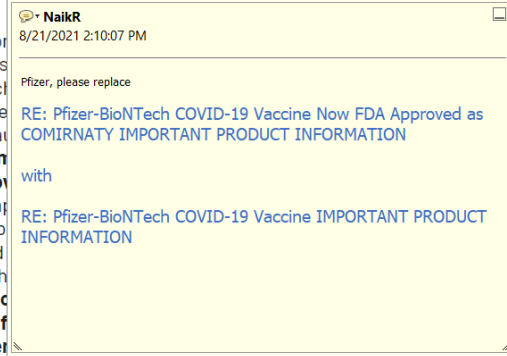
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

COMIRNATY
(COVID-19 Vaccine, mRNA)

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

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 the Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech COVID-19 Vaccine (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License. Certain Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized under the EUA. **Some of these lots are not BLA for COMIRNATY and are therefore considered "BLA-approved for individuals 16 years of age and older."** The lots that are BLA-approved for individuals 16 years of age and older may be found at [cvdvaccine-us.com/resources](https://www.cvdvaccine-us.com/resources). For these lots, please refer to the full prescribing information for indication and usage, dosing and safety information. This information can be found by scanning the QR code. **It is imperative that you not discard any available EUA lots. These lots are for use under EUA in individuals 12 years of age and older, and for immunocompromised individuals. You can continue to use these lots.**



Sincerely,

Donna Boyce

Senior Vice President, Global Regulatory Affairs

BIONTECH

Pfizer

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