

Review Slip

IND Number : EUA 27034 Submission : 29-APR-2021  
Amendment Number : 154 Serial Number :-1 eCTD # :0155 FDA Receipt Dt : 29-APR-2021  
CBER Receipt Dt : 29-APR-2021

Types : EUA/ OTHER/ Revised Full EUA PI

IND Title : Human Coronavirus mRNA Vaccine (SARS-CoV-2 Spike Protein; BNT162b2) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol) (Pfizer-BioNTech COVID-19 Vaccine)

Proposed Use : Prevention of COVID-19 in individuals 16 years of age and older

Sponsor : BioNTech Manufacturing GmbH (in partnership with Pfizer Inc)

ROUTE TO:

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DECISION : ☐ NO ACTION INDICATED ☒ ACTION REQUIRED ☐ MEMO ATTACHED

Specify action required or comments below (up to 4000 characters):

Revised Fact Sheet for Vaccination Providers and Full EUA Prescribing Information. In this amendment, Pfizer submitted their revised Fact Sheet for Vaccination Providers and Full EUA Prescribing Information in response to April 23, 2021 and April 28, 2021 comments.

Below are SharePoint links for the tracked-changes Word version and annotated pdf versions.

EUA 27034.154 Fact Sheet for Vaccination Providers-Full EUA PI ? track-changes Word

EUA 27034.154 Fact Sheet for Vaccination Providers-Full EUA PI ? annotated pdf

The amendment was routed to the clinical reviewers (Susan Wollersheim and Lucia Lee) and the APLB reviewer (Oluchi Elekwachi) in BIRAMS, and informed in an email message, on April 29, 2021.

Signature Information :

569494	RAMACHANDRA NAIK	29-Apr-2021 19:54:49	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra  
Naik -S

Digitally signed by Ramachandra  
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Date: 2021.04.29 19:55:16 -04'00'