

Review Slip

IND Number : EUA 27034 Submission : 03-MAY-2021
Amendment Number : 161 Serial Number :-1 eCTD # :0162 FDA Receipt Dt : 03-MAY-2021
CBER Receipt Dt : 03-MAY-2021

Types : EUA/ OTHER/ Response to 4/30/2021 clinical-OBE IR

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:

DIVISION	NAME	ADDRESS	PHONE
DVRPA	NAIK, RAMACHANDRA (G)	HFM-3221	796-2640

ALSO ROUTED TO :

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

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

Response to April 30, 2021 clinical-OBE IR regarding physical exam findings, case narratives for subjects with psychiatric diagnoses and deep vein thrombosis. In this amendment, Pfizer submitted their response to April 30, 2021 clinical-OBE IR regarding physical exam findings, case narratives for subjects with psychiatric diagnoses and deep vein thrombosis.

The amendment was routed to the clinical reviewers (Susan Wollersheim and Lucia Lee) and the OBE reviewer (Kerry Welsh) in BIRAMS, and informed in an email message, on May 3, 2021.

Signature Information :

569777	RAMACHANDRA NAIK	03-May-2021 11:39:06	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra
Naik -S

Digitally signed by Ramachandra
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Date: 2021.05.03 11:39:33 -04'00'