

Review Slip

IND Number : EUA 27034 Submission : 27-APR-2021
Amendment Number : 148 Serial Number :-1 eCTD # :0149 FDA Receipt Dt : 27-APR-2021
CBER Receipt Dt : 27-APR-2021

Types : EUA/ OTHER/ Response to 4/25/2021 clinical 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 :

DIVISION	NAME	ADDRESS	PHONE
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402
DVRPA	LEE, LUCIA H (C)	HFM-3333	796-1425

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IND Primary Reviewer :	NAIK, RAMACHANDRA (G)	Phone :	796-2640
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	SMITH, MICHAEL J (S)	Phone :	796-1569
	GOTTSCHALK, LAURA (S)	Phone :	796-2640

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

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

Response to April 25, 2021 clinical IR regarding safety follow-up time and case narratives for adverse events/serious adverse events after administration of Pfizer-BioNTech COVID-19 Vaccine.

The amendment was routed to the clinical reviewers (Susan Wollersheim and Lucia Lee) in BIRAMS, and informed in an email message, on April 27, 2021.

Signature Information :

568881	RAMACHANDRA NAIK	27-Apr-2021 11:01:32	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra
Naik -S

Digitally signed by Ramachandra
Naik -S
Date: 2021.04.27 11:02:09 -04'00'