

Review Slip

IND Number : EUA 27034 Submission : 03-MAY-2021
Amendment Number : 160 Serial Number :-1 eCTD # :0161 FDA Receipt Dt : 03-MAY-2021
CBER Receipt Dt : 03-MAY-2021

Types : EUA/ FACT SHEET (PROVIDER)/ REVISED

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	LEE, LUCIA H (C)	HFM-3333	796-1425
DB	HUANG, LEI (B)	HFM-5333	796-1983
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402

Primary Division :	DVRPA	Office :	OVRR
IND Primary Reviewer :	NAIK, RAMACHANDRA (G)	Phone :	796-2640
CSO :	SENN, KEVIN (S)	Phone :	796-1802
	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):

In this amendment, Pfizer submitted the revised Fact Sheet for Vaccination Providers-Full EUA PI that addresses CBER's April 30, 2021.

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

Signature Information :

569762	RAMACHANDRA NAIK	03-May-2021 10:52:24	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra Naik
-S
Digitally signed by Ramachandra Naik -S
Date: 2021.05.03 10:52:52 -04'00'