

Review Slip

IND Number : EUA 27034 Submission : 08-DEC-2020  
Amendment Number : 19 Serial Number : -1 eCTD # :0020 FDA Receipt Dt : 08-DEC-2020  
CBER Receipt Dt : 08-DEC-2020

Types : EUA/ OTHER/ Updated VRBPAC Presentation

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	LEE, LUCIA H (C) Lucia H. Lee -S	HFM-3333	796-1425

ALSO ROUTED TO :

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

Signature Information :

567526	LUCIA H LEE	18-Apr-2021 00:29:58	LEEL
Serial Number	Signed Name	Date Time	System ID