

Review Slip

IND Number : EUA 27034 Submission : 27-NOV-2020
Amendment Number : 4 Serial Number : -1 eCTD # :0005 FDA Receipt Dt : 27-NOV-2020
CBER Receipt Dt : 27-NOV-2020

Types : EUA/ OTHER/ Response to 11/23/20 IR clinical questions and asymptomatic
EUA/ OTHER/ Response to 11/24/20 discussion points for 11/25/20 t-con re

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
DB	HUANG, LEI (B)	HFM-5333	796-1983
DVRPA	BALDWIN, BRENDA (R)	HFM-3333	796-1626
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402

Primary Division :	DVRPA	Office :	OVR
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):

See Division approval memo.

Signature Information :

567517	LUCIA H LEE	18-Apr-2021 00:13:48	LEEL
Serial Number	Signed Name	Date Time	System ID