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Review Slip

IND Number : EUA 27034 **Submission :** 30-NOV-2020
Amendment Number : 6 **Serial Number :** -1 **eCTD # :**0007 **FDA Receipt Dt :** 30-NOV-2020
CBER Receipt Dt : 30-NOV-2020

Types : EUA/ OTHER/ Responses to November 25, 2020, IR regarding the PVP.

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 Digitally signed by Lucia H. Lee -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Lucia H. Lee -S, 0.9.2342.19200300.100.1.1=13001 47270 Date: 2021.04.18 00:18:49 -04'00'	HFM-3333	796-1425

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402
DVRPA	NAIK, RAMACHANDRA (G)	HFM-3221	796-2640
DE	WELSH, KERRY (O)	HFM-5221	402-8714
DE	NAIR, NARAYAN (O)	HFM-1335	796-0863

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 : [X] NO ACTION INDICATED [ ] ACTION REQUIRED [ ] MEMO ATTACHED

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

Signature Information :

567519	LUCIA H LEE	18-Apr-2021 00:18:14	LEEL
Serial Number	**Signed Name**	**Date Time**	**System ID**