

Review Slip

IND Number : EUA 27034 Submission : 01-DEC-2020
Amendment Number : 7 Serial Number : -1 eCTD # :0008 FDA Receipt Dt : 01-DEC-2020
CBER Receipt Dt : 01-DEC-2020

Types : EUA/ OTHER/ 398 page table of subjects w/ symptoms, but not PCR +
EUA/ OTHER/ Responses to 11/27 clinical IR's

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) <small>Lucia H. Lee -S Digitally signed by Lucia H. Lee -S DN: cn=Lucia H. Lee -S, o=FDA, ou=CDER, email=lee.luciah@fda.hhs.gov, c=US Date: 2021.04.18 00:20:02 -0400</small>	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

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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 :

567520	LUCIA H LEE	18-Apr-2021 00:20:02	LEEL
Serial Number	Signed Name	Date Time	System ID