

Review Slip

IND Number : EUA 27034 Submission : 09-DEC-2020  
Amendment Number : 21 Serial Number : -1 eCTD # :0022 FDA Receipt Dt : 09-DEC-2020  
CBER Receipt Dt : 09-DEC-2020

Types : EUA/ OTHER/ Additional clinical efficacy analysis for severe cases  
EUA/ OTHER/ Updated Fact Sheets and Full EUA PI

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)	HFM-3333	796-1425

Lucia H.  
Lee -S

Digitally signed by Lucia H. Lee -S  
DN: cn=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
cn=Lucia H. Lee -S,  
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210  
Date: 2021.04.18 00:32:27 -0400

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
DVRPA	NAIK, RAMACHANDRA (G)	HFM-3221	796-2640
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402

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	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):

Comments for fact sheets sent.

Signature Information :

567527	LUCIA H LEE	18-Apr-2021 00:31:27	LEEL
Serial Number	Signed Name	Date Time	System ID