

Review Slip

IND Number : EUA 27034 Submission : 25-NOV-2020
Amendment Number : 3 Serial Number : -1 eCTD # :0004 FDA Receipt Dt : 25-NOV-2020
CBER Receipt Dt : 25-NOV-2020

Types : EUA/ OTHER/ Response to IRs Dated 11/17/2020 & 11/19/2020
EUA/ OTHER/ Updated Emergency Use Full Prescribing Information
EUA/ OTHER/ VRBPAC Briefing Document

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:			
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DECISION : ☐ NO ACTION INDICATED ☒ ACTION REQUIRED ☐ MEMO ATTACHED

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

Comments sent for Fact sheet.

Signature Information :			
567516	LUCIA H LEE	18-Apr-2021 00:10:55	LEEL
Serial Number	Signed Name	Date Time	System ID