

Review Slip

IND Number : EUA 27034 Submission : 11-DEC-2020
Amendment Number : 27 Serial Number : -1 eCTD # :0028 FDA Receipt Dt : 11-DEC-2020
CBER Receipt Dt : 11-DEC-2020

Types : EUA/ OTHER/ In response to CBER's 12/11/20 comments
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:

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

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

Comments for fact sheet sent.

Signature Information :

567531	LUCIA H LEE	18-Apr-2021 00:36:07	LEEL
Serial Number	Signed Name	Date Time	System ID