

Review Slip

IND Number : EUA 27034 Submission : 20-NOV-2020
Amendment Number : 0 Serial Number : eCTD # :0001 FDA Receipt Dt : 20-NOV-2020
CBER Receipt Dt : 20-NOV-2020

Types : ORIGINAL SUBMISSION

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):

Please see Division memo.

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Signature Information :

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Serial Number	Signed Name	Date Time	System ID