

Review Slip

IND Number : EUA 27034 Submission : 10-DEC-2020
Amendment Number : 23 Serial Number : -1 eCTD # :0024 FDA Receipt Dt : 10-DEC-2020
CBER Receipt Dt : 10-DEC-2020

Types : EUA/ FACT SHEET (PROVIDER)/ REVISED
EUA/ FACT SHEET (RECIPIENT)/ REVISED
EUA/ OTHER/ Revised Fact Sheets and FullEUA PI from 12/9/20
EUA/ OTHER/ Thermal Shipping Container Dry Ice Replenishment Instruction
EUA/ OTHER/ Thermal shipping container dry ice replenishment instruction

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 |
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| ALSO ROUTED 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 : | | | |
|-------------------------|-------------|----------------------|-----------|
| 567529 | LUCIA H LEE | 18-Apr-2021 00:33:07 | LEEL |
| Serial Number | Signed Name | Date Time | System ID |