

Review Slip

IND Number : EUA 27034 Submission : 04-DEC-2020
Amendment Number : 12 Serial Number : -1 eCTD # :0013 FDA Receipt Dt : 04-DEC-2020
CBER Receipt Dt : 04-DEC-2020

Types : EUA/ OTHER/ Response to two IR dated 2 December 2020

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=LUCIA H. LEE, o=FDA, ou=FDA, ou=People,
email=Lucia.H.Lee@FDA.gov, c=US
Date: 2021.04.18 00:24:04 -0400

ALSO ROUTED TO :

| DIVISION | NAME | ADDRESS | PHONE |
|----------|------------------------|----------|----------|
| DVRPA | NAIK, RAMACHANDRA (G) | HFM-3221 | 796-2640 |
| DE | WELSH, KERRY (O) | HFM-5221 | 402-8714 |
| DVRPA | WOLLERSHEIM, SUSAN (C) | HFM-3221 | 402 |

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|------------------------|-----------------------|----------|----------|
| Primary Division : | DVRPA | Office : | OVRR |
| IND Primary Reviewer : | NAIK, RAMACHANDRA (G) | Phone : | 796-2640 |
| CSO : | SENN, KEVIN (S) | Phone : | 796-1802 |
| | 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):

See Division approval memo.

Signature Information :

| | | | |
|---------------|-------------|----------------------|-----------|
| 567522 | LUCIA H LEE | 18-Apr-2021 00:24:04 | LEEL |
| Serial Number | Signed Name | Date Time | System ID |