

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:

DIVISION NAME

DE

WELSH, KERRY (O)

Kerry J.

Welsh -S

Digitally signed by Kerry J. Welsh -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Kerry J. Welsh -
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0.9.2342.19200300.100.1.1=2001896608
Date: 2020.12.15 08:35:44 -05'00'

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

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

OBE/DE Pharmacovigilance Review

Signature Information :

549781

KERRY WELSH

15-Dec-2020 08:33:11

KERRY.WELSH

Serial Number

Signed Name

Date Time

System ID