

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	ADDRESS	PHONE
DVP	WANG, XIAO (P)	HFM-1315	402-7466

Xiao Wang -S

Digitally signed by Xiao Wang -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
cn=Xiao Wang -S,
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Date: 2020.12.18 15:48:33 -05'00'

ALSO ROUTED TO :

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DE	NAIR, NARAYAN (O)	HFM-1335	796-0863
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DVP	MURATA, HARUHIKO (P)	HFM-1315	827-0650
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DMPQ	JONES, KATHLEEN R (M)		796-7950
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DECISION : ☒ NO ACTION INDICATED ☐ ACTION REQUIRED ☒ MEMO ATTACHED

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

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Signature Information :

550608	XIAO WANG	18-Dec-2020 15:45:39	WANGXIA
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