

Review Slip

IND Number : EUA 27034 Submission : 09-APR-2021
Amendment Number : 132 Serial Number :-1 eCTD # :0135 FDA Receipt Dt : 09-APR-2021
CBER Receipt Dt : 09-APR-2021

Types : EUA/ FACT SHEET (PROVIDER)/ REVISED
EUA/ FACT SHEET (RECIPIENT)/ REVISED
EUA/ OTHER/ Extend Authorization for Individuals 12-15 Years of Age
EUA/ OTHER/ PHARMACOVIGILANCE PLAN, CRFs, DATA SETS
EUA/ OTHER/ Response to IR dated 31 MAR 2021

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
DE	WELSH, KERRY (O)	Kerry J. Welsh -S	HFM-5221	402-8714

Digitally signed by Kerry J. Welsh -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Kerry J. Welsh -S,
0.9.2342.19200300.100.1.1=2001896608
Date: 2021.05.07 16:09:06 -04'00'

ALSO ROUTED TO :				
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DVRPA	NAIK, RAMACHANDRA (G)		HFM-3221	796-2640
DVRPA	LEE, LUCIA H (C)		HFM-3333	796-1425
DVRPA	WOLLERSHEIM, SUSAN (C)		HFM-3221	402
DIS	KANNAN, BHANUMAHTI (O)		HFM-5015	827-6188
DVRPA	BALDWIN, BRENDA (R)		HFM-3333	796-1626
DB	HUANG, LEI (B)		HFM-5333	796-1983
DCM	ELEKWACHI, OLUCHI (I)		HFM-4141	827-6331

Primary Division :	DVRPA	Office :	OVRR
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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):

Signature Information :

570633	KERRY WELSH	07-May-2021 16:08:01	KERRY.WELSH
Serial Number	Signed Name	Date Time	System ID