

Review Slip

IND Number : EUA 27034 Submission : 11-DEC-2020
Amendment Number : 25 Serial Number :-1 eCTD # :0026 FDA Receipt Dt : 11-DEC-2020
CBER Receipt Dt : 11-DEC-2020

Types : EUA/ OTHER/ Response to IR dated 10 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	NAIK, RAMACHANDRA (G)	HFM-3015	796-2640

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
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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

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

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

Response to December 10, 2020 IR.

On December 10, 2020, CBER requested the Sponsor to submit to the EUA a document that explains the relationship between Pfizer, Inc. and BioNTech Manufacturing GmbH. This document should explain how Pfizer is assuring oversight of the aspects of the manufacturing process conducted by BioNTech and any other entity responsible for any aspect of manufacturing.

In this amendment 25, Pfizer-BioNTech submitted their response to the IR regarding relationship between Pfizer Inc. and BioNTech Manufacturing GmbH.

Signature Information :

550109	RAMACHANDRA NAIK	16-Dec-2020 14:11:30	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra Naik
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Digitally signed by Ramachandra Naik -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=2001232361,
cn=Ramachandra Naik -S
Date: 2020.12.16 14:12:12 -05'00'