

Review Slip

IND Number : EUA 27034 Submission : 22-APR-2021  
Amendment Number : 145 Serial Number :-1 eCTD # :0146 FDA Receipt Dt : 22-APR-2021  
CBER Receipt Dt : 22-APR-2021

Types : EUA/ OTHER/ Response to 4/20/2021 IR reg dataset analysis programs and .

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:

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	GOTTSCHALK, LAURA (S)	Phone :	796-2640

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

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

Response to April 20, 2021 IR regarding data analysis programs and datasets. In this amendment, Pfizer submitted their response to April 20, 2021 statistical IR regarding data analysis programs and datasets.

The amendment was routed to the statistical reviewer (Lei Huang) in BIRAMS, and informed in an email message, on April 22, 2021.

Signature Information :

568273	RAMACHANDRA NAIK	22-Apr-2021 13:11:14	NAIKR
Serial Number	Signed Name	Date Time	System ID

Ramachandra  
Naik -S

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: 2021.04.22 13:11:54 -04'00'