

Review Slip

IND Number : EUA 27034 Submission : 30-NOV-2020
Amendment Number : 5 Serial Number :-1 eCTD # :0006 FDA Receipt Dt : 30-NOV-2020
CBER Receipt Dt : 30-NOV-2020

Types : EUA/ OTHER/ Revised VRBPAC briefing document

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

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

In this amendment the sponsor is providing Response to FDA 23 November 2020 IR and Response to FDA 24 November 2020 IR in Module 1.11.3.

Signature Information :

549802	NABIL AL-HUMADI	15-Dec-2020 10:23:44	ALHUMADIN
Serial Number	Signed Name	Date Time	System ID

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=2000429963, cn=Nabil H. Al-humadi -S
Date: 2020.12.15 10:24:49 -05'00'