

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:

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

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
DVRPA	NAIK, RAMACHANDRA	HFM-3221	796-2640
DVRPA	WOLLERSHEIM, SUSAN		
DVRPA	LEE, LUCIA H	HFM-3333	796-1425
DE	WELSH, KERRY	HFM-5221	402-8714
DVP	MURATA, HARUHIKO	HFM-1315	827-0650
DB	HUANG, LEI (B)	HFM-5333	796-1983
DVRPA	AL-HUMADI, NABIL	HFM-3221	796-1369
DE	NAIR, NARAYAN	HFM-1335	796-0863

Primary Division :	DRMRR	Office :	OVRR
IND Primary Reviewer :	SMITH, MICHAEL (CBER) J (G)	Phone :	796-1569
CSO :	SENN, KEVIN (S)	Phone :	796-1802
	CLIFFORD, JULIANNE (S)	Phone :	827-3070
	SMITH, MICHAEL (CBER) J (S)	Phone :	796-1569
	MAGUIRETHON, MEGHAN (S)	Phone :	

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

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

This amendment contained the updated Briefing Document in support of the VRBPAC meeting held on December 10, 2020. A minor revision was made in Figure 7 to substitute the graph of B1 data in older adults with a graph of the neutralization data for B2 in older adults. The text and the graph are consistent.

No action is needed.

Xiao Wang -S
Digitally signed
by Xiao Wang -S
Date: 2024.03.12
22:05:28 -04'00'

This document contains Sensitive But Unclassified (SBU) information and is intended FOR OFFICIAL USE ONLY. The contents are not intended for public release. Do not disseminate, distribute, or share with persons not authorized to receive such information. All sensitive data must be properly labeled prior to dissemination to authorized persons.

Review Slip

Signature Information :

682044	XIAO WANG	12-Mar-2024 22:04:57	WANGXIA
Serial Number	Signed Name	Date Time	System ID