

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
DVRPA	NAIK, RAMACHANDRA (G)	HFM-3221	796-2640

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
DVRPA	LEE, LUCIA H (C)	HFM-3333	796-1425
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402
DCM	ELEKWACHI, OLUCHI (I)	HFM-4141	827-6331
DIS	KANNAN, BHANUMAHTI (O)	HFM-5015	827-6188
DB	HUANG, LEI (B)	HFM-5333	796-1983
DE	WELSH, KERRY (O)	HFM-5221	402-8714
DVRPA	BALDWIN, BRENDA (R)	HFM-3333	796-1626

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

GOTTSCHALK, LAURA (S)

Phone : 796-2640

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

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

EUA Amendment to expand the emergency use of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12-15 years of age.

The amendment was routed to the clinical reviewers (Lucia Lee and Susan Wollersheim), statistical reviewer (Lei Huang), APLB reviewer (Oluchi Elekwachi), OBE reviewer (Kerry Welsh), data standards reviewer (Brenda Baldwin) and the BIMO reviewer (Bhanu Kannan) in BIRAMS, and informed in an email message, on April 9, 2021.

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: 2021.04.09 22:33:10 -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 :

566325	RAMACHANDRA NAIK	09-Apr-2021 22:32:08	NAIKR
Serial Number	Signed Name	Date Time	System ID