

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	BALDWIN, BRENDA	(R)	Brenda R. Baldwin -S	796-1626

Digitally signed by Brenda R. Baldwin -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300391961,
cn=Brenda R. Baldwin -S
Date: 2021.07.20 14:26:06 -0400

ALSO ROUTED TO :				
DIVISION	NAME		ADDRESS	PHONE
DVRPA	NAIK, RAMACHANDRA	(G)	HFM-3221	796-2640
DVRPA	LEE, LUCIA H	(C)	HFM-3333	796-1425
DVRPA	WOLLERSHEIM, SUSAN	(C)	HFM-3221	402
DIS	KANNAN, BHANUMAHTI	(O)	HFM-5015	827-6188
DB	HUANG, LEI	(B)	HFM-5333	796-1983
DE	WELSH, KERRY		HFM-5221	402-8714
DCM	ELEKWACHI, OLUCHI	(I)	HFM-4141	827-6331

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):

Pfizer submitted this amendment to the EUA to extend the authorization to individuals 12-15 years of age. The data presented in this EUA amendment from pivotal study C4591001 (conducted under IND 19736) consists of the immune response measured by SARS-CoV-2 neutralizing antibody titers in this adolescent group compared to young adults 16-25 years of age, which serves as immunobridging for adolescents; efficacy data in the 12-15 years of age group; and safety data in approximately 2200 adolescents with a median follow-up time of at least 2 months after Dose 2. Additionally, safety data in adolescents are compared to the larger data safety data set of individuals 16-55 years of age. The datasets also contain the information from the adult portion of the study.

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

On April 14, 2021, the eDATA team discussed the validation results with the review committee for EUA 27034 amendment 132. One study's datasets were validated ? C4591001 which included all 48,901 subjects. There were no major dataset concerns as the data were much cleaner. The datasets were additionally validated for only those subjects 55 years of age and younger (n=29, 417).

Signature Information :

579481	BRENDA BALDWIN	20-Jul-2021 14:25:21	BALDWIN
Serial Number	Signed Name	Date Time	System ID