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Review Slip

IND Number : IND 19736 Submission : 03-AUG-2021
Amendment Number : 434 Serial Number : -1 eCTD # :0434 FDA Receipt Dt : 03-AUG-2021
CBER Receipt Dt : 03-AUG-2021

Types : ADMINISTRATIVE/ REQUEST FROM SPONSOR/ Request for Comments and Advice ? Adolescent BLA Proposal
OTHER/ OTHER/ Request for comments & Advice - sBLA adolescents 12-15 yoa

IND Title : Human Coronavirus mRNA Vaccines (SARS-CoV-2 Spike Protein; BNT162a1 (uRNA; variant RBL063.3);
BNT162b1 (modRNA; variant RBP020.3); BNT162b2 (modRNA; variant RBP020.2); BNT162c2 (saRNA;
variant RBS004.2)) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol)

Proposed Use : Prophylactic immunization for COVID-19 infection in adults 18 years of age and older
Sponsor : BioNTech SE

ROUTE TO:

DIVISION	NAME	ADDRESS	PHONE
DVRPA	NAIK, RAMACHANDRA (G)	HFM-3221	796-2640

ALSO ROUTED TO :

DIVISION	NAME	ADDRESS	PHONE
DB	HUANG, LEI (B)	HFM-5333	796-1983
DVRPA	WOLLERSHEIM, SUSAN (C)	HFM-3221	402

Primary Division : DVRPA Office : OVRR
 IND Primary Reviewer : NAIK, RAMACHANDRA (G) Phone : 796-2640
 CSO : SENN, KEVIN (S) Phone : 796-1802

DECISION : NO ACTION INDICATED ACTION REQUIRED MEMO ATTACHED

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

Request for Comments and Advice ? Proposal for adolescent (12-15 yoa) sBLA. In this amendment, Pfizer-BioNTech submitted a Request for Comments and Advice regarding a proposal to submit a supplemental Biologics License Application (sBLA) to extend the age group to include adolescents 12 through 15 years of age.

Pfizer is requesting CBER's feedback regarding the acceptability of their proposed clinical package to support a sBLA no later than August 17, 2021.

The amendment was routed to the clinical reviewer (Susan Wollersheim) and the statistical reviewer (Lei Huang) in BIRAMS, and informed in an email message, on August 3, 2021.

Signature Information :

581445	RAMACHANDRA NAIK	03-Aug-2021 21:21:17	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: 2021.08.03 21:21:56 -04'00'