

**CBER Receipt Dt : 09-APR-2021**

**Sponsor :** BioNTech Manufacturing GmbH (in partnership with Pfizer Inc)

DIVISION	NAME	ADDRESS	PHONE
DB	HUANG, LEI (B)	HFM-5333	796-1983

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
DVRPA	BALDWIN, BRENDA (R)	HFM-3333	796-1626
DE	WELSH, KERRY (O)	HFM-5221	402-8714
DCM	ELEKWACHI, OLUCHI (I)	HFM-4141	827-6331

<b>Primary Division :</b>	DVRPA	<b>Office :</b>	<b>OVR</b>
<b>IND Primary Reviewer :</b>	NAIK, RAMACHANDRA (G)	<b>Phone :</b>	796-2640
<b>CSO :</b>	SENN, KEVIN (S)	<b>Phone :</b>	796-1802
	SMITH, MICHAEL J (S)	<b>Phone :</b>	796-1569
	GOTTSCHALK, LAURA (S)	<b>Phone :</b>	796-2640

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

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

Pfizer submitted Amendment 132 to EUA 27034 to extend the EUA to individuals 12-15 years of age. The statistical review memo is attached.

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 :

570429	LEI HUANG	06-May-2021 13:38:09	LEI.HUANG
Serial Number	Signed Name	Date Time	System ID

Lei  
Huang -S

Digitally signed by Lei Huang -S  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
cn=Lei Huang -S,  
0.9.2342.19200300.100.1.1=2001  
932785  
Date: 2021.05.06 13:41:00 -04'00'