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IND Number : EUA 27034 Submission : 25-NOV-2020
Amendment Number : 3 Serial Number : -1 eCTD # :0004 FDA Receipt Dt : 25-NOV-2020
CBER Receipt Dt : 25-NOV-2020

Types : EUA/ OTHER/ Response to IRs Dated 11/17/2020 & 11/19/2020
EUA/ OTHER/ Updated Emergency Use Full Prescribing Information
EUA/ OTHER/ 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)

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

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

This amendment contained the following documents:

1. A briefing document in support of the VRBPAC meeting held on December 10, 2020.
2. Response to CBER Information Requests issued on November 17, 2020, regarding 508 compliant tables for the EUA submission and on November 19, 2020, regarding inclusion of the baseline SARS-CoV-2 infection status in the Demographic Characteristics Table 13.
3. Updated Emergency Use full prescribing information.

From a CMC perspective, no action is indicated.

Xiao Wang -S
Digitally signed by Xiao Wang -S
Date: 2024.03.12 21:51:17 -04'00'

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