May 13, 2022

Please Note,

A review of PRB records indicates that there are no pending lots or issues that would affect the approval of the stated STN.

125742/45

Leyla P. Beshir -S
Digitally signed by Leyla P. Beshir -S
Date: 2022.05.13 11:21:53 -04'00'

Biologist, Product Release Branch

CBER/OCBQ/DMPQ

WO, Building 71, Room 6062
240-402-9165 (main)/ 240-402-5839 (office)
Leyla.beshir@fda.hhs.gov
Lot Release Information

U.S. FOOD & DRUG ADMINISTRATION

From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 7:52 PM
To: CBER Lot Clearance <cberlotclearance@fda.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Subject: OVRR: Lot Clearance Request for STN 125742/45

Please confirm that there are no pending lot release issues that would prevent approval of this efficacy supplement.

- **Applicant Name:** BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
- **Product Names:** COVID-19 Vaccine, mRNA (COMIRNATY)
- **License Number:** 2229
- **Address:** BioNTech Manufacturing GmbH, An der Goldgrube 12 Mainz, GERMANY
- **Application #:** 125742/45
- **Submission type:** Efficacy supplement
- **Action Due Date:** June 17, 2022, but we may take action by the end of May
- **Summary:** For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adolescents 12 through 15 years of age.

Thanks,

Laura

Laura Gottschalk, PhD
Regulatory Project Manager/Primary Reviewer

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-0798
laura.gottschalk@fda hhs.gov