August 17, 2021

Please Note,

The lots below are associated with this Supplement.

STN	Supp. #	License Number	Company	Product	Lot Type	Lot Number	Sample Received Date
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FD7220	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FE3592	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FF2587	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FF2588	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FF2590	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FF2593	17 Aug 2021
125742	0	2229	BioNTech Manufacturing GmbH	COVID-19	FC	FF8841	17 Aug 2021

The lot(s) associated with this BLA/supplement will be released upon completion of protocol review, any requested sample testing and approval of the BLA/supplement.

Since lots are associated with this BLA/supplement please be sure to provide a copy of the signed approval to the Product Release Branch by fax to 301.594.6924 or e-mail the letter to CBER Lot Clearance.

Biologist, Product Release Branch
CBER/OCBQ/DMPQ
WO, Building 71, Room G6062
240-402-9165 (main)/ 240-402-5839 (office)/301-595-1253 (fax)
Lot Release Information

From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 10:49 AM
To: CBER Lot Clearance <cberlotclearance@fda.gov>; Beshir, Leyla <Leyla.Beshir@fda.hhs.gov>
Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Eichelberger, Maryna <Maryna.Eichelberger@fda.hhs.gov>; Quander III, Joseph <Joseph.Quander@fda.hhs.gov>; Hulme, Cheryl <Cheryl.Hulme@fda.hhs.gov>
Subject: OVRR: Lot Clearance Request for STN 125742/0 - Please Respond by COB Thursday
Importance: High

Dear Lot Clearance,

Please confirm that there are no lots associated with this Submission. Please note, although the official action due date is January 16, 2022, we are aiming to approve within the week. Therefore, please provide a response by **COB Thursday, Aug 19.**

The lots are supposed to be received today. I have cc'ed some of the DBSQC team here in case they would like to provide any clarification or answer any questions that you may have.

- **Applicant Name:** BioNTech Manufacture GmbH (in partnership with Pfizer, Inc.)
- **License Number:** 2229
- **Company Address:** An der Goldgrube 12
  Mainz, Germany 55131
- **Application STN:** 125742/0
- **Product Name:** COVID-19 Vaccine, mRNA (COMIRNATY)
- **Submission Type:** Original Application (Priority 8 Month)
- **Action Due Date:** January 16, 2022 (please see note above)
- **Short Summary:** For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Thanks in advance and please let us know if you have any questions.

Best,
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