August 17, 2021

Please Note,

The lots below are associated with this Supplement.

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<tr>
<th>STN</th>
<th>Supp. #</th>
<th>License Number</th>
<th>Company</th>
<th>Product</th>
<th>Lot Type</th>
<th>Lot Number</th>
<th>Sample Received Date</th>
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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.
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