From: CBER Complicheck <complicheck@fda.hhs.gov>
Sent: Friday, July 1, 2022 11:42 AM
To: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; CBER Complicheck <complicheck@fda.hhs.gov>
Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>
Subject: RE: OVRR: Expedited Compliance Check Request for STN 125742/45

- **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:** Target ADD of **next Friday, July 8, 2022** (Previously June 17, 2022)
- **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.

List of manufacturing locations affected by the changes identified in the supplement:

1. Pharmacia & Upjohn Company LLC (Pfizer)
   7000 Portage Road
   Kalamazoo, MI 49001
   FEI#: 1810189

2. Pfizer Manufacturing Belgium NV
   Rijksweg 12
   Puurs, Belgium 2870
   FEI#: 1000654629

3. Hospira, Inc
   1776 North Centennial Drive
   McPherson, Kansas 67460
   FEI# 1925262

There are no ongoing or pending investigations or compliance actions with respect to the above facility or its product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this supplement.

Daniel DeCiero
Consumer Safety Officer

OCBQ/DCM/BDDCB
WO71, Room 5011B
240-402-1666

From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Monday, June 27, 2022 5:38 PM
To: CBER Complicheck <complicheck@fda.hhs.gov>
Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>
Subject: OVRR: Expedited Compliance Check Request for STN 125742/45

Please execute a compliance check for the following 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
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Thank you,

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
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