Laura B. Gottschalk -S
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Date: 2022.07.05 11:08:02 -04'00'

From: Gottschalk, Laura
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
- **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

Thank you,

Laura

Laura Gottschalk, PhD
Regulatory Project Manager/Primary Reviewer

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