From: Smith, Michael (CBER)
Sent: Thursday, May 20, 2021 10:24 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: STN 125742/0: IR RE facilities

Elisa, Neda and Carmel,

The BLA review committee has the below facilities information requests for you:

1. Please submit an updated manufacturing schedule for June 1 through October 31, 2021, that details upstream and downstream operations for BNT162b2 drug substance manufacturing in both (b) (4) and (b) (4) at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC facility (FEI: 1222181) in Andover, MA in support of BLA 125742/0.

2. Please submit an updated manufacturing schedule for June 1 through October 31, 2021, that details lipid nanoparticle formulation and fill/finish operations for BNT162b2 drug product manufacturing at both Pfizer Manufacturing Belgium NV facility (FEI: 1000654629) in Puurs, Belgium and Pharmacia & Upjohn Company LLC. facility (FEI: 1810189) in Kalamazoo, MI in support of BLA 125742/0. Please include production schedules for each filling line.

3. Please provide clarification regarding (b) (4) of the Puurs, Belgium facility. As noted in the BLA Section 3.2.R Manufacturing Schedules, production of the COVID-19 vaccine may not be occurring during these timeframes: May 31, 2021, – June 06, 2021, and July 10, 2021,- Sept 06, 2021. Please provide clarification if this applies to all COVID-19 vaccine manufacturing (formulation and/or fill/finish) or select operations.

4. Please provide the COVID-19 precautions taken at each manufacturing facility related to visitor entry requirements. At a minimum, please include the maximum number of visitors/inspectors and the necessity of vaccine status/negative COVID-19 test result for entry into your facility.

Please provide this information by Monday May 24, 2021, and please provide a time early next week, preferably Tuesday, May 25, 2021, or Wednesday,
May 26, 2021, for a teleconference to discuss production schedules and the shutdown activities planned for the Puurs, Belgium site.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration

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