From: Smith, Michael (CBER)
Sent: Tuesday, August 17, 2021 2:13 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Subject: STN 125742.0: IR on DS

Elisa,

The review team has the below questions on the drug substance and they have requested a response as soon as possible and no later than COB Wednesday, August 18, 2021.

1. In your drug substance (DS) manufacturing process validation studies performed at both Pfizer (b) (4) and Pfizer (b) (4), the process parameter for the (b) (4) was validated to be within the range of (b) (4) However, in your documents Section 3.2.S.2.2 Manufacturing Process Andover and Section 3.2.S.2.4 Controls of Critical Steps and Intermediates - Manufacturing Process, the (b) (4) is described as (b) (4). Please align the acceptance range of this process control parameter in all the documents based on your validation study results.

2. Please update the Tables 3.2.P.3.4-1 in Sections 3.2.P.3.4 Process Step (b) (4) – (b) (4) – Puurs and Kalamazoo, to include the validated (b) (4) for DS (b) (4) using (b) (4) based on your qualification/validation data submitted to BLA 125742 amendment 33 in response to our August 3, 2021 Information Request query 4.

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
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2@fda.hhs.gov