From: Smith, Michael (CBER)
Sent: Wednesday, August 18, 2021 2:36 PM
To: Rohlfing, Paul <Paul.Rohlfing@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>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742.0: IR on DS

Paul,

The review team provided me the below response to your e-mail:

The proven acceptance range (PAR) of 0-35 minutes for the (b) (4) (b) (4) is acceptable. Meanwhile, we acknowledge that a target range of (b) (4) (b) (4) for the (b) (4) (b) (4) will remain in the Andover batch records for both manufacturing sites (b) (4) b) 4)

Regards,

Mike

From: Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Sent: Wednesday, August 18, 2021 10:07 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; 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: [EXTERNAL] RE: STN 125742.0: IR on DS
Importance: High

Mike,

Regarding the comments on (b) (4) (b) (4) we would ask the review team to consider the relevant supporting information provided in 3.2.S.2.6 Manufacturing Process Development-Process Development and Characterization of the BLA. We have provided relevant information from that document below.

The (b) (4) (b) (4) was studied as a (b) (4) experiment with a range of (b) (4) . The study design and results are described 3.2.S.2.6

Manufacturing Process Development-Process Development and Characterization and the results are shown in the table below copied from the BLA.

(b) (4)

(b) (4)

Please confirm receipt of this email. I am available to discuss this issue further with you or members of the review team in order to reach quick resolution.

Regards,

Paul Rohlfing
Executive Director GCMC Vaccines
Pfizer

(b) (6) - mobile
(919) 566-4927 - office
Paul.rohlfing@pfizer.com

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
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: [EXTERNAL] 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) (b) (4) the process parameter for the (b) (4) (b) (4) was validated to be within the range of (b) (4) . However, in your documents Section 3.2.S.2.2 Manufacturing (b) (4) Process, the (b) (4) (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) – (b) (4) (b) (4) – Puurs and Kalamazoo, to include the validated for DS (b) (4) using both the (b) (4) (b) (4) (b) (4) (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
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