From: Smith, Michael (CBER)
Sent: Friday, August 6, 2021 11:31 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: RE: STN 125742.0: IR RE two DP documents

Elisa,

The review team has the below questions regarding the following two drug product (DP) documents 1) Manufacturing Process Development – Process Development and Characterization and 2) Description of Manufacturing Process and Process Controls – LNP Production and Bulk Drug Product Formulation [Puurs]. The review team has requested a response by Tuesday, August 10, 2021.

We note the following statement quoted below in your document 3.2.P.2 Manufacturing Process Development – Process Development and Characterization on page 47:
"For more efficient processing, the (b) (4) *software at Pfizer Puurs was updated to introduce a* (b) (4) *step, independent of the selected batch size,* (b) (4) *"*
This (b) (4) step was validated in coupled with the process validation for a drug product batch size (b) (4) (b) (4) at Pfizer Puurs (data submitted to EUA 27034 amendment 116 on March 29, 2021). However, the process validation for the (b) (4) batch size was not executed with this (b) (4) step. Please clarify that during the routine commercial-scale manufacturing process, the (b) (4) step is only applied to the (b) (4) batch scale at Pfizer Puurs. Please also update the document 3.2.P.3.3 Description of Manufacturing Process and Process Controls – LNP Production and Bulk Drug Product Formulation [Puurs] to clearly describe at which batch scale the (b) (4) step will be performed.

Regards,

Mike

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

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