

From: Wang, Hsiaoling <Hsiaoling.Wang@fda.hhs.gov>
Sent: Monday, August 30, 2021 3:10 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Sutkowski, Elizabeth M. <Elizabeth.Sutkowski@fda.hhs.gov>; Eichelberger, Maryna <Maryna.Eichelberger@fda.hhs.gov>; Pan, Tao <Tao.Pan@fda.hhs.gov>; Francis, Kori <Kori.Francis@fda.hhs.gov>
Subject: RE: STN 125742.0.41: Response to DBSQC IR RE testing related limits for established (b) (4) and polydispersity index

Hi Mike:

I reviewed the amendment 41 (received on 8/11/2021) and it is acceptable. The data (established limits for the control) was used in DLStest memo, which I uploaded on 8/20/2021.

Thank you,

Charlene

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Monday, August 30, 2021 2:53 PM
To: Wang, Hsiaoling <Hsiaoling.Wang@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Sutkowski, Elizabeth M. <Elizabeth.Sutkowski@fda.hhs.gov>; Eichelberger, Maryna <Maryna.Eichelberger@fda.hhs.gov>; Pan, Tao <Tao.Pan@fda.hhs.gov>; Francis, Kori <Kori.Francis@fda.hhs.gov>
Subject: STN 125742.0.41: Response to DBSQC IR RE testing related limits for established (b) (4) and polydispersity index

Charlene,

Pfizer submitted amendment 41 on August 11th in response to your August 10th IR, but I don't see that you mention that in your review (attached). Can you please respond to this e-mail and indicate that you reviewed amendment 41 submitted on August 11, 2021, and found their response to be acceptable?

Thanks,

Mike