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 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 DLS test 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 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