

From: Jones, Kathleen (CBER) <Kathleen.Jones1@fda.hhs.gov>
Sent: Monday, August 30, 2021 5:26 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Peters, Lori <Lori.Peters@fda.hhs.gov>; Fontan, Laura <Laura.Fontan@fda.hhs.gov>; Price, Gregory <Gregory.Price@fda.hhs.gov>; Lynch, Christian <Christian.Lynch@fda.hhs.gov>; Emerson, Debra <Debra.Emerson@fda.hhs.gov>; Eltermann, John <John.Eltermann@fda.hhs.gov>; Renshaw, Carolyn <Carolyn.Renshaw@fda.hhs.gov>; Allen, Ekaterina <Ekaterina.Allen@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>
Subject: RE: STN 125742.0.60: revised 483 responses for the Andover site

Mike,

This is not mentioned in the combined memo. It is covered in the 483 response memo. There is no need for additional follow-up with Pfizer, their response was acceptable. Thank you and have a good day.

Kathy

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Monday, August 30, 2021 3:25 PM
To: Peters, Lori <Lori.Peters@fda.hhs.gov>; Jones, Kathleen (CBER) <Kathleen.Jones1@fda.hhs.gov>; Fontan, Laura <Laura.Fontan@fda.hhs.gov>; Price, Gregory <Gregory.Price@fda.hhs.gov>; Lynch, Christian <Christian.Lynch@fda.hhs.gov>; Emerson, Debra <Debra.Emerson@fda.hhs.gov>; Eltermann, John <John.Eltermann@fda.hhs.gov>; Renshaw, Carolyn <Carolyn.Renshaw@fda.hhs.gov>; Allen, Ekaterina <Ekaterina.Allen@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>
Subject: STN 125742.0.60: revised 483 responses for the Andover site

Lori and the DMPQ team,

Pfizer submitted amendment 60 on August 18th containing updated responses to the FDA form 483 that was issued to the Andover site in response to the August 17th t-con that we had w/ them, but I don't see that mentioned in your combined review. Can you please respond to my e-mail indicating that you reviewed amendment 60 and found their response to be acceptable?

Mike