

From: Smith, Michael (CBER)

Sent: Tuesday, May 18, 2021 6:02 PM

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: STN 125742/0: IR RE datasets

Elisa, Neda and Carmel,

The BLA review committee has the below IR for you regarding datasets.

Reference is made to amendment 132 (dated April 9, 2021) to your EUA 27034, the teleconference held on April 8, 2021, and roll 1 of your BLA STN 125742/0 (dated May 6, 2021).

1. Please confirm that the datasets submitted in the EUA 27034-amendment 132 are identical to the datasets submitted to BLA STN 125742/0.
2. Please confirm that the datasets submitted as SDTM-SUPPL and ADaM-SUPPL contain the reactogenicity data changes as requested (including flags) in the teleconference held on April 8, 2021 and nothing additional.
3. Please clarify what data was changed in the supplemental EX and DM datasets.

Please provide your response by COB tomorrow, May 19, 2021.

Also, please note that a teleconference with Pfizer may be needed for more clarifications on the datasets. We will contact you regarding the possible dates and times for a teleconference with you.

Regards,

Mike

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

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