From: Smith, Michael (CBER)
Sent: Wednesday, August 18, 2021 2:51 PM
To: 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>; 'Rohlfing, Paul' <Paul.Rohlfing@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; 'Aghajani Memar, Neda' <Neda.AghajaniMemar@pfizer.com>; 'Devlin, Carmel M' <Carmel.Devlin@pfizer.com>
Subject: STN 125742.0: DBSQC comments

Elisa and Paul,

Our review of the information provided in your BLA STN 125742/0 for COMIRNATY (COVID-19 Vaccine, mRNA), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. We have the following comments in response to your recent submissions:

1. In amendment 54 to BLA STN 125742/0 (Seq 0056, dated 08/17/2021), you agreed to perform an endotoxin test (b) (4) and explained you will establish the method and perform verification studies at your drug product release testing facilities. Please submit information and data to support this method along with a draft updated lot release protocol template, to CBER as a CBE-30 supplement in accordance with 21 CFR 601.12(c). Please acknowledge our request and keep us updated on the progress of your studies so we can anticipate the submission. If you would like to engage in further discussions, please let us know.

2. In amendment 50 to BLA STN 125742/0 (Seq 0050, dated 08/16/2021) you stated that you would include specific parameters/instructions for (b) (4) in the CGE integrity test method (TM100010392). Please acknowledge that you will submit the revised SOP to your IND 19736. The difference in (b) (4) used in assay validation and Lot Release Protocols submitted to CBER recently (lots FD7220, FE3592 and FF2587) indicates that a requirement for a specific (b) (4) has not been established, giving the appearance that your current method allows for (b) (4) parameters that could potentially result in (b) (4) (b) (4). Since there is (b) (4), we recommend you include instructions on what actions to take when (b) (4)

(b) (4) to minimize (b) (4) and ensure consistency of the method. We encourage you to perform robustness studies with varied sample preparation and instrument conditions to decide on the optimal parameters. Please contact CBER if you wish to discuss your approach.

Please provide an acknowledgement of the above requests in an amendment to your BLA 125742/0 by 12:00pm August 19, 2021.

Regards,

Mike

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

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Captain, USPHS

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