From: Smith, Michael (CBER) Sent: Friday, July 9, 2021 4:46 PM

To: Harkins Tull, Elisa <Elisa. Harkins Tull@pfizer.com>; Aghajani Memar, Neda <Neda. Aghajani Memar@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 the validation of the RNA Integrity by capillary gel electrophoresis (CGE)

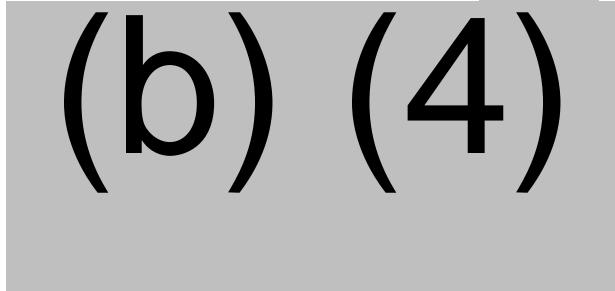
method

Elisa,

The review team has three questions for you regarding the validation of the RNA Integrity by capillary gel electrophoresis (CGE) method - see below.

We are reviewing your Biologics License Application (STN 125742/0) submitted on May 18, 2021, for your BNT162b2 vaccine and have the following Information Request (IR) regarding the validation of the RNA Integrity by capillary gel electrophoresis (CGE) method (VAL100136603-v2). Please respond by providing the requested data or your plans to address these requests, by July 23, 2021.

1. Please describe the spiked materials used for evaluating the (b) (4)

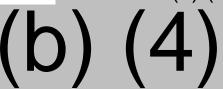


2. The acceptance criterion for the assay Range evaluation is stated as (b) (4)



Please comment and provide additional data to support your proposed acceptance criterion for the RNA integrity Range evaluation.

3. You stated on Page 31 that the assay quantitation limit (QL) was (b) (4) determined from the results



study. Please explain.

Regards,

Mike

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

Mike Smith, Ph.D. Captain, USPHS

Senior Regulatory Review Officer Food and Drug Administration Center for Biologics Evaluation & Research Office of Vaccines Research & Review **Division of Vaccines and Related Products Applications**

Tel: 301-796-2640

michael.smith2@fda.hhs.gov











THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone. hone.