

From: Smith, Michael (CBER)

Sent: Friday, July 9, 2021 4:46 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 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)

(b) (4)

2. The acceptance criterion for the assay Range evaluation is stated as

(b) (4)

(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 determined from the results (b) (4)

(b) (4)

study. Please explain.

Regards,

Mike

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

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