From: Smith, Michael (CBER)
Sent: Wednesday, August 4, 2021 11:00 AM
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 potency assay for determination of IVE by flow cytometry

Elisa,

The review team has two questions for you regarding the potency assay for determination of in vitro expression (IVE) by flow cytometry. The review team has requested a response by Friday, August 6, 2021.

The following comments pertain to the Report for Co-validation of Test Method TM100010380 – Determination of the In-vitro Expression of PF-07302048 (BNT162b2 Construct, Drug Product) by Flow Cytometry (VAL100147509).

1. You reported an overall percent relative standard deviation (%RSD) of (b) (4) in Table 12-5 on Page 14 of the report. However, our calculation results in an overall %RSD (b) (4) using the Mean S1+% data from this table. Please explain how you calculated the overall %RSD for (b) (4)

2. We note that, in Tables 14-1 and 14-2 on Page 21 of the report, the mean S1+ (%) results from (b) (4) compared to the results from (b) (4) . This trend becomes more (b) (4) , which may indicate some systematic difference between (b) (4) . Please comment and explain why you consider reproducibility to be acceptable given this observation.

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