Michael J. Smith -S4
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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0014080934, cn=Michael J. Smith -S4
Date: 2022.03.14 09:20:14 -04'00'

From: Smith, Michael (CBER)
Sent: Monday, March 14, 2022 9:17 AM
To: Collins, Kathleen Mary Catherine (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Mineo, Gosia (b) (6) Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742/45 – Comirnaty sBLA – F/U Clinical-statistical question to Pfizer's response to our 3/7 comments regarding updated immunobridging analyses and solicited adverse reaction frequencies

Kate,

The review team has a follow-up question to Pfizer's response that was submitted in STN 125742.45.4 in response to the review team's 3/7/22 clinical and statistical questions.

You state that no additional reactogenicity data have been recorded in the e-diary since the EUA. However, we note that the numbers of placebo subjects who reported any headache, chills, and diarrhea post Dose 2 are 263, 73, and 43, respectively in the SDTM (1 Month Follow-up) datasets and the draft prescribing information, while the respective counts appear to be 264, 74, and 44 in the SDTM (6 Month Follow-up) datasets. Please clarify the discrepancy and provide updated reactogenicity tables as appropriate.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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