

Michael J. Smith -S4
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Michael J. Smith -S4
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From: Smith, Michael (CBER)
Sent: Wednesday, May 4, 2022 10:25 AM
To: Collins, Kathleen Mary Catherine (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <meghan.maguirethon@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: IR RE placebo recipient information contained in the PI

Kate,

The review team has the below information request regarding placebo recipient information contained in the Package Insert (PI) that was submitted to STN 125742.45 and they requested a response by Monday, May 9th.

Please confirm the number of placebo recipients who reported nausea from Dose 1 through 1 month after Dose 2, based on the September 2, 2021 data cutoff. There appears to be 2 placebo recipients who reported nausea from Dose 1 through 1 month post Dose 2, based on our analysis of the 6-mo ADAE dataset.

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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