

From: Smith, Michael (CBER)
Sent: Friday, August 13, 2021 6:22 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742.0: 3rd set of PI labeling comments

Neda,

We have the attached 3rd set of comments on the Package Insert (PI). Please e-mail us the further revised PI (both Word tracked-changes and Word annotated) by noon Monday, August 16, 2021, and follow up with a submission to the BLA. Please note that we will have additional comments for you on the PI next week.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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