

**From:** Smith, Michael (CBER)  
**Sent:** Tuesday, August 17, 2021 6:11 PM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
**Cc:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>  
**Subject:** STN 125742.0: 4th set of PI labeling comments

Elisa,

I attached the 4<sup>th</sup> set of comments on the Package Insert (PI). Please e-mail us the further revised PI (both Word tracked-changes and Word annotated) by 12:00 PM Wednesday, August 18, 2021, and follow up with a submission to the BLA.

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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