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Sent: Thursday, August 19, 2021 12:54 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
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Subject: STN 125742.0: 6th set of PI labeling comments - please respond by COB today

Dear Elisa,

Attached is the 6th set of comments from the review team on the Package Insert (PI). Please email us the further revised PI (both Word tracked-changes and Word annotated) by COB today, August 19, 2021, and follow up with a submission to the BLA.

Please acknowledge receipt and let me know if you have any questions.

Best,
Laura

Laura Gottschalk, PhD

Regulatory Project Manager/Primary Reviewer

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