

From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:37 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
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Subject: STN 125742.0: 8th set of PI labeling comments - please respond by 3:00pm today

Dear Elisa,

Attached is the 8th 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 3:00pm today, August 21, 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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