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Sent: Thursday, August 5, 2021 3:37 PM
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Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: STN 125742.0: Second round of PI comments

Elisa,

Please find attached the second round of labeling comments on the Package Insert (PI) from the review team. The review team has requested a response by COB Monday, August 9, 2021.

Regards,

Mike

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

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