

From: Gottschalk, Laura
Sent: Sunday, August 22, 2021 10:28 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: STN 125742/0 - Final Draft Label: Package Insert

Dear Ms. Harkins,

We have reviewed your draft Package Insert (PI) label submitted in Amendment 74 to your BLA 125742, dated August 21, 2021 (STN 125742/0.74; Seq 0076) and found it to be acceptable. CBER considers the clean version of the PI included in Amendment 74 as the Final Draft Label for approval.

Best regards,
Laura

Laura Gottschalk, PhD

Regulatory Project Manager/Primary Reviewer

Center for Biologics Evaluation and Research
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