

From: Gottschalk, Laura
Sent: Thursday, July 22, 2021 8:52 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Subject: STN 125742/0: IR regarding clinical shell tables for study C4591001

Dear Ms. Harkins,

Reference is made to your original BLA STN 125742/0. Attached, please find CBER's information request regarding clinical shell tables for study C4591001. As noted in the document, please provide your responses in an amendment to STN 125742/0 by **COB Monday, July 26, 2021**.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Best regards,
Laura

Laura Gottschalk, PhD

Regulatory Project Manager/Primary Reviewer

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