Laura B. Gottschalk -S
2021.09.20 15:13:08 -04'00'

From: Gottschalk, Laura
Sent: Monday, September 20, 2021 3:05 PM
To: Patel, Amit <Amitkumar.Patel@pfizer.com>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; (b) (6) ; adrienne.stafford@pfizer.com; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: STN 125742/9 - COVID-19 Vaccine, mRNA (COMIRNATY): Product Correspondence - CBER response to plan for reporting Biologic Product Deviation Reports

Dear Mr. Patel,

We refer you to your Product Correspondence submitted and received on September 15, 2021 to STN 125742/9 to request comments and advice for reporting of Biologic Product Deviation Reports to the EUA as well as to the BLA. We agree with your plan for reporting of Biological Product Deviation Reports to the BLA and including any affected EUA lots in those reports, as described in your STN 125742/9 submission.

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

Best regards,
Laura

Laura Gottschalk, PhD
Regulatory Project Manager/Primary Reviewer

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