

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Monday, August 16, 2021 5:26 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Boyce, Donna <Donna.Boyce@pfizer.com>
Subject: STN 125742/0 – COMIRNATY – Submission of CMC information to support extension of shelf life of BNT162b2 to 9 months

Dear Ms. Harkins,

Reference is made to the amendment 260 to your EUA 27034 (dated August 13, 2021) that contains the CMC information in support of extension of shelf-life of the undiluted drug product for up to 9 months. Please submit this same CMC stability information to your BLA STN 125742 so that we can consider a 9-month shelf-life for the licensed product. We are reviewing the data under EUA 27034, but we want it formally submitted to the BLA.

Please submit this information to STN 125742/0 by COB Tuesday, August 17, 2021.

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

Regards,
Ram

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