From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Friday, April 8, 2022 10:50 AM
To: Mineo, Gosia (b) (6)
Cc: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Collins, Kathleen Mary Catherine (b) (6); Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>
Subject: STN 125742/45 - Comirnaty sBLA to to extend the indication to adolescents 12 through 15 years of age - CBER comment regarding Tris/Sucrose formulation

Michael J. Smith -S4 Digitally signed by Michael J. Smith -S4 Date: 2022.04.08 10:57:22 -04'00'

Dear Ms. Mineo,

We have the following request for additional information regarding the sBLA STN 125742/45 submission for extending licensure of COMIRNATY to adolescents 12 through 15 years of age.

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(b) (4) In this sBLA submission, it appears that only the PBS/Sucrose formulation of COMIRNATY is requested for licensure in adolescents 12 through 15 years of age. Please confirm that you only intend to seek licensure for the 30-microgram dose of PBS/Sucrose formulation in adolescents 12 through 15 years of age and please provide the rationale for not including the Tris/Sucrose formulation of the same dosage in the submission.

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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