

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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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

Ramachandra S. Naik, Ph.D.

Biologist (Regulatory) / Primary Reviewer
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