From: Naik, Ramachandra
Sent: Tuesday, July 13, 2021 5:11 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>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742/0 - COMIRNATY – CBER comments regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative

Dear Ms. Harkins,

Our review of the information provided in your BLA STN 125742/0 for COMIRNATY (COVID-19 mRNA Vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. COMIRNATY is supplied in a multiple-dose vial that does not contain a preservative. Please note that 21 CFR 610.15(a) requires that "Products in multiple-dose containers shall contain a preservative,…" The regulations in 610.15(d) permit the approval of an exception or alternative to this requirement. Requests for such exceptions or alternatives must be in writing. Your submission does not include a request for an exception or alternative to the requirement of a preservative. Therefore, please submit a request and a justification for an exception or alternative to the requirement under 21 CFR 610.15(a) that products in multiple-dose vials include a preservative.

Please provide your response in an Amendment to STN 125742/0, as soon as possible.

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

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