

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 BLASTN 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

Ramachandra S. Naik, Ph.D.
Biologist (Regulatory) / Primary Reviewer
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
ramachandra.naik@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.