

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Saturday, August 21, 2021 2:18 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Boyce, Donna <Donna.Boyce@pfizer.com>
Subject: STN 125742/0 – COMIRNATY – CBER comments regarding label for identification of BLA lots and Dear HCP Letter

Dear Ms. Harkins,

Our review of the information provided in your BLA STN 125742 for COMIRNATY (COVID-19 Vaccine, mRNA) indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. Please see the attached for CBER's comments regarding the draft Dear HCP Letter included in amendment 73 (dated August 20, 2021).

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

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

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



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