

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Friday, August 20, 2021 2:23 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Rohlfing, Paul <Paul.Rohlfing@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Boyce, Donna <Donna.Boyce@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
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 mRNA Vaccine), 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 and revisions regarding the information included in amendment 64 (dated August 19, 2021) about the label to include with the vaccine tray package and the draft Dear HCP Letter.

Please refer to our August 20, 2021, 2:08 PM email communication regarding lots that you consider to be BLA-compliant, and confirm that EUA-labeled "lots in the field" will not be listed at [cvdvaccine-us.com/resources](https://www.cvdvaccine-us.com/resources) until they are released by CBER.

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

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