

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>

Sent: Wednesday, August 18, 2021 6:58 PM

To: Boyce, Donna <Donna.Boyce@pfizer.com>

Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura

<Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M

<Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Rohlfing,

Paul <Paul.Rohlfing@pfizer.com>

Subject: BLA STN 125742/0 – COMIRNATY (COVID-19 Vaccine, mRNA) – Identification of BLA-compliant lots and Letter to HCP

Dear Donna,

Reference is made your August 16, 2021 email communication and telephone conversation with Mary Malarkey, Director, OCBQ/FDA, in which you shared a graphic for identification of BLA-compliant lots and draft Dear HCP Letter. Please submit these and any relevant documents as an amendment to the BLA.

If these documents have already been submitted, please point us to the amendment/sequence number and when these were submitted.

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

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.