

From: Naik, Ramachandra
Sent: Friday, August 20, 2021 2:08 PM
To: Boyce, Donna <Donna.Boyce@pfizer.com>
Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: RE: Lot Numbers for the COVID Launch Lots [BLA STN 125742/0 - COMIRNATY]

Dear Donna,

Thank you for the information!

Please note that we do not consider these EUA-labeled “lots in the field” to comply with the BLA at this time since lot release activities have yet to be agreed upon and performed. We will work with you to develop a lot release approach after the initial BLA approval occurs. Please ensure that these “lots in the field” are not listed in the [cdvaccine-us.com/resources](https://www.cdvaccine-us.com/resources) website included in the Dear HCP Letter (submitted in draft as amendment 64 to the BLA on August 19, 2021). We will provide comments on the Dear HCP Letter in a separate communication.

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



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.

From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Thursday, August 19, 2021 6:49 PM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Naik, Ramachandra

<Ramachandra.Naik@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>;
Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Subject: RE: [EXTERNAL] Lot Numbers for the COVID Launch Lots

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear All,

Attached please find the list of lots in the field that comply with the BLA. We do not have visibility to the consumption/inventory of these lots so cannot say how many doses per lots remain.

Also, we have not shipped any doses from the 7 “launch lots.” These are planned for shipment in Sept. Therefore, the ^{(b) (4)} million dose remain in our control.

Please contact me with any questions.

Kind regards,

Donna

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Sent: Thursday, August 19, 2021 5:37 PM

To: Boyce, Donna <Donna.Boyce@pfizer.com>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>;
Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Cc: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>;
Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>

Subject: RE: [EXTERNAL] Lot Numbers for the COVID Launch Lots

Dear Donna

Thanks so much for this! I think we have these lots in house now. I probably wasn't clear to Peter that we were still waiting to get the other lots in the field that would be considered BLA compliant. It would be very helpful to get a list of those and some idea of magnitude. I presume the seven lots have diminished from the ^{(b) (4)} million doses at this point.

We will also have comments on the Dear HCP.

Thanks again

Mary

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

Sent: Thursday, August 19, 2021 5:33 PM

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

Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>;
Rohlfing, Paul <Paul.Rohlfing@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>

Subject: [EXTERNAL] Lot Numbers for the COVID Launch Lots

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ram,

I understand from Peter Marks that the CBER review team is looking for the lot numbers of the launch lots.

These are the seven Lot Numbers:

1. FD7220
2. FE3592
3. FF2587
4. FF2588
5. FF2590
6. FF2593
7. FF8841

Please contact me with any questions.

Kind regards

Donna