

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:29 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Cc: Boyce, Donna <Donna.Boyce@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] BLA 125742/0 Status of any additional requests

Dear Elisa,

Thank you for sending/submitting responses to our comments quickly.

- We do not have any additional comments on the Dear HCP letter.
- We are not planning to send any comments or requests regarding Package Insert tonight.
- We are reviewing information regarding PMC-PMR studies.
- Revision to the EUA Fact Sheets is ongoing. If they are ready, we will send them tonight.

Regards,
Ram

-----Original Message-----

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Saturday, August 21, 2021 5:08 PM
To: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Cc: Boyce, Donna <Donna.Boyce@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] BLA 125742/0 Status of any additional requests

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, Mike & Laura,

For today's requests (USPI Round 8; PMRs/PMCs; Dear HCP Letter) all have been responded to via email and formally submitted. Please advise if we should anticipate any additional requests tonight. Please also see my earlier request sent to Laura checking on the status of the revised EUA prescribing information/fact sheets and VIS-like document.

Best regards,
Elisa