

Michael J. Smith -S4 Digitally signed by
Michael J. Smith -S4
Date: 2022.07.05
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From: Smith, Michael (CBER)

Sent: Wednesday, June 29, 2022 10:35 AM

To: 'Mineo, Gosia' (b) (6)

Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>; 'Devlin, Carmel M' <Carmel.Devlin@pfizer.com>; 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>; 'Corpuz, Katherine' (b) (6)

Subject: STN 125742/45: Request for resubmission of PI w/ 7/2022 added for the date under "recent major changes" and "revision date"

Gosia,

We acknowledge receipt of the revised Package Insert (PI) that was submitted to STN 125742/45 on May 13, 2022. Please resubmit it to the BLA on Friday, July 1, 2022, and replace "M/YYYY" with "7/2022" for the date under "recent major changes" and "revision date" on page one of the highlights page (three instances). Please do not make any other changes to the PI.

Regards,

Mike

- Please confirm receipt of this email and let us know if you have any questions.

Mike Smith, Ph.D.

Captain, USPHS

Senior Regulatory Review Officer

Food and Drug Administration

Center for Biologics Evaluation & Research

Office of Vaccines Research & Review

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