

From: Smith, Michael (CBER)

Sent: Tuesday, July 5, 2022 10:51 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: Final Draft Label of Pl's

Michael J. Smith -S4
Digitally signed by Michael J. Smith -S4
Date: 2022.07.05 11:02:05 -04'00'

Gosia,

We have reviewed the Package Inserts that were submitted in Amendment 13 to STN 125742/45 on Friday, July 1st and we found them to be acceptable. CBER considers the clean versions of the Pls included in Amendment 13 as the Final Draft Labels for approval.

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
Division of Vaccines and Related Products Applications
Tel: 301-796-2640

michael.smith2@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 immediately by e-mail or phone.