Michael J. Smith -S4 Digitally signed by Michael J. Smith -S4 Date: 2022.06.14 08:01:54 -04'00'

From: Smith, Michael (CBER)
Sent: Monday, June 13, 2022 4:28 PM
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>
Subject: STN 125742/45: Delay in the review of this efficacy supplement

Dear Ms. Mineo:

Please reference the COVID-19 Vaccine, mRNA (CORMIRNATY) Efficacy Supplement STN 125742/45, that you submitted on December 16, 2021 for active immunization to prevent coronavirus disease 2019 (COVID 19) caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) in adolescents 12 through 15 years of age.

In response to the Coronavirus Disease 2019 (COVID-19) public health emergency, FDA's Center for Biologics Evaluation and Research (CBER) has taken steps to prioritize work that advances the nation's response during this national emergency. Therefore, we will not be able to meet the goal date of June 17, 2022, for your submission referenced above. We will continue to review your submission as time and resources allow and will notify you of our final action upon completion of our review.

For additional information regarding CBER operations during this public health emergency, please see the CBER COVID-19 CBER Regulated Biologics page found at https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics and guidance for industry, *Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – Questions and Answers* at https://www.fda.gov/media/138358/download.

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

Regards,

Mike

Mike Smith, Ph.D.
Captain, USPHS

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