Michael J. Smith -S4
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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0014080934, cn=Michael J. Smith -S4
Date: 2022.02.23 15:08:38 -05'00'

From: Smith, Michael (CBER)
Sent: Wednesday, February 23, 2022 3:06 PM
To: Collins, Kathleen Mary Catherine (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Mineo, Gosia (b) (6) Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742.45: IR RE Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age

Kate,

We are reviewing the Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age (BLA 125742/45, Module 5.3.6, dated December 1, 2021; received December 16, 2021) and have the following information requests.

1. The cumulative analysis shows 18 adverse events reports with fatal outcomes among individuals 12-15 years of age. Please provide preferred terms and narratives for each of these fatal reports and indicate how many and which of the reports were U.S. vs foreign.

2. The cumulative analysis indicates that 1,215 serious reports were received for individuals 12-15 years of age. Please provide the number of serious reports that were U.S. vs. foreign.

Please provide a response to this information request by COB March 1, 2022.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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