

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=001408
0934, cn=Michael J. Smith -S4
Date: 2021.05.06 14:56:30 -04'00'

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Thursday, May 6, 2021 10:40 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: [EXTERNAL] RE: EUA 27034: IR RE participants w/ depression & serotonin reuptake inhibitor (SSRI) medication. Response requested ASAP

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Dear Mike,

We do not capture routine concomitant medication in the case report form, so we are unable to provide the information requested.

Best regards,
Elisa

Elisa Harkins
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Global Regulatory Affairs - Vaccines
Pfizer, Inc.
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Collegeville, PA 19426

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From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Thursday, May 6, 2021 9:52 AM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: [EXTERNAL] EUA 27034: IR RE participants w/ depression & serotonin reuptake inhibitor (SSRI) medication. Response requested ASAP

Neda, Elisa and Carmel,

Reference is made to the amendment 132 (dated April 9, 2021) to EUA 27034 to extend the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 through 15 years of age. We have the following Information Request (IR):

For participants 12 through 15 years of age with prior history of depression, please provide the number and percentage of subjects being treated w/ selective serotonin reuptake inhibitor (SSRI) medication and start/stop dates relative to depression diagnosis.

The review team would like this information ASAP. Therefore, please e-mail us your responses as soon as you can and preferably by 2:00 PM today. Additionally, please follow-up by submitting identical information in an amendment to the EUA, by COB today.

Regards,

Mike

- Please confirm receipt of this email and let me know if you have any questions or need additional information.

Mike Smith, Ph.D.
Captain, USPHS

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Food and Drug Administration
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