

From: Smith, Michael (CBER)
Sent: Tuesday, July 13, 2021 3:31 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; 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: STN 125742.0: IR RE the Pharmacovigilance Plan

Elisa,

The review team has the below Information Request regarding the Pharmacovigilance Plan (PVP):

We note that myocarditis and pericarditis are not included in the PVP. However, the current EUA Fact Sheet includes Warnings for myocarditis and pericarditis. Therefore, please add myocarditis and pericarditis to the PVP as an important identified risk and submit a revised PVP as an amendment to BLA 125742 by July 19, 2021.

Regards,

Mike

- Please confirm receipt of this e-mail 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



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