From: Smith, Michael (CBER)
Sent: Monday, August 16, 2021 10:38 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Subject: STN 125742.0: IR RE diluent suppliers

Elisa,

The review team has the below information request for you regarding your diluent suppliers:

Due to the Warning Letter (reference WL 320-20-31 issued 03/25/2020) and Official Action Indicated status of Pfizer Healthcare India Pvt. Ltd. (FEI# 3008316085), the Agency will not approve the diluent supplied from that manufacturer as part of your BLA. Please acknowledge this notification and remove all references to this supplier from the BLA, including in the recently added Diluent Manufacturers table.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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