

From: Smith, Michael (CBER)

Sent: Friday, August 13, 2021 12:32 PM

To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>

Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>

Subject: STN 125742.0: Requests and instructions regarding test methods, the lot release process, and the lot release protocol template

Importance: High

Neda and Paul,

The CBER DBSQC team has the attached requests and instructions regarding test methods, the lot release process, and the lot release protocol template. Please respond to this information request as soon as possible and preferably today.

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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