

**From:** Smith, Michael (CBER)  
**Sent:** Tuesday, August 10, 2021 1:11 PM  
**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:** STN 125742.0: Testing related IR

Neda,

The review team has the below testing related IR and they have requested a response by Wednesday, August 11, 2021.

Please provide the established <sup>(b) (4)</sup> and polydispersity index limits for the control lot of PF-07302048-DP-RM for the test of “Size and polydispersity Index Measurement in mRNA LNP Samples by Dynamic Light Scattering” for drug product.

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**  
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