

From: Smith, Michael (CBER)

Sent: Thursday, August 5, 2021 3:13 PM

To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>

Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>

Subject: STN 125742.0: Diluent questions

Elisa,

The review team has the below questions regarding the diluent.

1. The BLA includes 4 pictures of the saline diluent that will be provided but shipped separately from the vaccine vials. Additional, information regarding the diluent does not appear to be included in the BLA. Based on the pictures provided, the saline diluent is provided in “2mL single dose” and “10mL single dose” vials.
 - a. With respect to the 2mL single dose vial of saline, we assume that the end user will extract 1.8mL to reconstitute a single vial of vaccine. Please confirm and provide the instructions provided with the diluent.
 - b. With respect to the 10mL single dose vial, please submit any instructions provided to healthcare providers.
2. Also, please clarify if providers can reconstitute 2 or more vials of vaccine with saline from a 10mL single dose vial.
3. Lastly, please provide the container/closure information for each of these vials and information regarding the number of permissible punctures of the vial stopper.
4. If the requested information above is provided in the BLA, please provide the section(s).

If possible, please email a response by 11:00 AM Monday, August 9, 2021, and follow-up with a submission to the BLA.

Regards,

Mike

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

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Captain, USPHS

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