

From: Smith, Michael (CBER)

Sent: Wednesday, August 11, 2021 10:27 AM

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: Diluent IR

Neda,

The review team has the below question regarding the diluent that is to be provided in the BLA. They have requested a response as soon as possible and no later than noon Friday, August 13, 2021.

1. In reference to the diluent that will be used with your COVID-19 vaccine (sterile 0.9% Sodium Chloride Injection, USP) “2 mL single dose” and “10 mL single dose” vials:
 - a. Please update Section 3.2.P.3.1. MANUFACTURER(S) of your BLA to include the manufacturers of each vial size, including their address and FEI numbers.
 - b. Please update FDA Form 356h to include the information related to your diluent manufacturers.
 - c. Please provide a summary of the shipping procedures for the “2 mL single dose” and “10 mL single dose” vials including the origin of distribution, shipping responsible party, carton sizes, description of the shipper (box) and shipping configuration, and the established shipping controls.

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



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.