From: Gottschalk, Laura
Sent: Friday, July 16, 2021 8:16 AM
To: 'Elisa.HarkinsTull@pfizer.com' <Elisa.HarkinsTull@pfizer.com>
Cc: 'Aghajani Memar, Neda' <Neda.AghajaniMemar@pfizer.com>; 'Carmel.Devlin@pfizer.com' <Carmel.Devlin@pfizer.com>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; 'Paul.Rohlfing@pfizer.com' <Paul.Rohlfing@pfizer.com>
Subject: STN 125742/0: IR RE LRP template and DS handling instructions

Dear Ms. Harkins,

The review team has the following comments for you regarding your lot release protocols and drug substance handling instructions. Please submit your responses to the BLA as soon as possible.

1. The lot release protocols previously submitted in amendments 125742/0.4 (dated May 24, 2021) and 125742/0.10 (dated July 9, 2021) need to be modified to be templates for use for all lots submitted to CBER. Lot release templates should be a preset format that does not state results.

   Please submit a lot release protocol template (no results stated) for the COVID-19 mRNA Vaccine for CBER review containing only the assays performed and acceptance criteria for the drug product.

   The header on each page of the template should state the following:

   cc: 000000 _0/Lic #/FC Page 1 of total # of pages
   Lot Number:
   License Name of Product:

   Please note; upon CBER review of the lot release protocol template, additional information may be requested.

2. We received three different lots of drug substance (DS) on July 09, 2021 to conduct testing at CBER. You provided one tube of frozen DS for each lot. Please provide instructions for thawing and any other conditions that we need to consider in making aliquots. Also, please state how many freeze-thaw cycles are acceptable. We would appreciate this response as soon as possible, but no later than July 20, 2021.

Please confirm receipt of this message and let us know if you have any questions.

Best,
Laura

Laura Gottschalk, PhD
Regulatory Project Manager/Primary Reviewer

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