From: Gottschalk, Laura
Sent: Friday, July 16, 2021 3:29 PM
To: Elisa.HarkinsTull@pfizer.com
Cc: 'Aghajani Memar, Neda' <Neda.AghajaniMemar@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
Subject: STN 125742/0: IR RE (b) (4) sterility and endotoxin methods

Dear Ms. Harkins,

Additional information is needed to complete our review of the (b) (4) sterility and endotoxin methods. Please submit your responses to the following requests by July 30, 2021.

1. Regarding the (b) (4) sterility method:
    a. Please confirm that both PGS-Puurs and PGS-KZO testing facilities will conduct (b) (4) of (b) (4) sterility tests since test results for (b) (4) were not optimal during the validation study.
    b. Please confirm that both PGS-Puurs and PGS-KZO testing facilities will conduct visual inspection for growth during the (b) (4) (b) (4).

2. Regarding the endotoxin test:
    a. Please submit complete verification reports of the endotoxin tests for interfering factors from both the PGS-Puurs and PGS-KZO facilities. These reports should include positive product control (PPC) percent recoveries for all drug product sample dilutions tested and the selected testing dilution that provided the optimal PPC percent recovery. In addition, the reports should identify the product lot numbers tested instead of referring to them as Trials 1, 2 and 3, as in the submitted summarized verification of bacterial endotoxins report.

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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