

**From:** Smith, Michael (CBER)

**Sent:** Friday, August 6, 2021 7:26 PM

**To:** 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>; 'Aghajani Memar, Neda' <Neda.AghajaniMemar@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: 3 questions RE measurement of endotoxins using the (b) (4) (b) (4) LAL procedures

Elisa,

The review team has the below three question for you regarding the measurement of endotoxins using the (b) (4) LAL procedures. They have requested a response as soon as possible and no later than Friday, August 13, 2021.

1. Your procedure for measuring endotoxin in Drug Product (DP) includes a (b) (4) " step. While you provide data demonstrating the (b) (4) (b) (4) does not impact the activity of endotoxin that is (b) (4) (b) (4), you have not provided data to evaluate the potential endotoxin-like activity of the (b) (4) (b) (4). Please provide data to address potential endotoxin-like activity of (b) (4) (b) (4) .
2. You state that the (b) (4) step is performed to (b) (4) (b) (4) is the usual approach to (b) (4) . Please provide data from a (b) (4) (b) (4) ).
3. From the data generated in the preceding request, we ask that you identify a (b) (4) for testing DP within the (b) (4) , (b) (4) . Please use this information to establish the endotoxin limit and establish a specification for DP endotoxin activity levels for samples that are (b) (4) . Please comment and provide a date by which results from the test using (b) (4) samples can be included for DP lot release, together with the endotoxin results for samples (b) (4) (b) (4)

Regards,

Mike

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

**Mike Smith, Ph.D.**  
**Captain, USPHS**

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