

From: Houck, Christina M
Sent: Tuesday, January 19, 2016 3:58 PM
To: KSmyth@paxvax.com
Cc: Hoffman, Kelsy
Subject: STN 125597 Information Request

Dear Mr. Smyth,

We have the following request for additional information for STN 125597:

1. We note the specification limit for (b) (4) and that the batch analysis of the conformance lots have shown results (b) (4). CBER requests an alert limit be added to the bioburden specification for the (b) (4), drug product and buffer to better track/trend your manufacturing process for improved quality oversight.
2. CBER requests that (b) (4) be qualified using (b) (4). Testing (b) (4) for (b) (4) drug product. Please submit the results for review.

Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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