

**From:** Houck, Christina M  
**Sent:** Thursday, February 04, 2016 9:03 AM  
**To:** KSmyth@paxvax.com  
**Cc:** Hoffman, Kelsy  
**Subject:** STN 125597 Information Request

Dear Mr. Smyth,

On January 19, 2016 an Information Request (IR) was submitted to PaxVax. We have one minor edit to that request and are submitting a new IR below. Please note the requests are identical except for one minor addition to item #2. When you submit your response, as an amendment to your BLA, please reference this IR dated February 4, 2016 as it will replace the January 19, 2016 IR.

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 the (b) (4), drug product and buffer. Please submit the results for review.

Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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