

**From:** Houck, Christina M  
**Sent:** Friday, February 26, 2016 8:57 AM  
**To:** KSmyth@paxvax.com  
**Cc:** Hoffman, Kelsy  
**Subject:** STN 125597 Information Request/Advice

Dear Mr. Smyth,

We have reviewed your February 12, 2016 submission (Amendment #7) for STN 125597 and have the following comments:

1. CBER requests the qualification report for (b) (4) Testing using (b) (4) for (b) (4) drug product and buffer, including (b) (4) be submitted before the end of May 2016, so that it can be reviewed in a timely manner before the Action Due Date (ADD) of June 15, 2016.
2. If the timeline for submission of this qualification report does not allow timely review prior to the ADD, please submit the report as a post-approval change in the form of a Prior Approval Supplement (PAS). We do not agree with your proposal of submitting the qualification report as a CBE/CBE-30. Please note, you will not be able to release any commercial lots of the vaccine until CBER reviews and approves the PAS.

Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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