

From: [Houck, Christina M](#)
To: ["KSmyth@paxvax.com"](mailto:KSmyth@paxvax.com)
Cc: [Hoffman, Kelsy](#)
Subject: STN 125597 IR
Date: Thursday, December 17, 2015 9:24:25 AM

Dear Mr. Smyth,

We are reviewing your BLA for STN 125597/0 for Cholera Vaccine, Oral, Live for "active immunization against disease caused by *V. cholerae* serogroup O1 in adults 18 years of age and older." After further review we have the following information request:

1. In sections 3.2.S.4.1 [REDACTED] 3.2.P.5.1 (drug product) of your submission, the bioburden specification for [REDACTED] [REDACTED] However, batch analysis of the conformance lots have shown results [REDACTED] [REDACTED] Please re-evaluate specifications to better track and trend the process capabilities of your manufacturing process to provide better quality oversight of the manufacturing process.
2. In section 3.2.P.5.1 (buffer) of your submission, the bioburden specification for [REDACTED] [REDACTED]. However, batch analysis of the conformance lots has shown results [REDACTED]. Please re-evaluate specifications to better track and trend the process capabilities of your manufacturing process to provide better quality oversight of the manufacturing process.
3. Please provide a justification for not testing [REDACTED] [REDACTED] (document numbers NG-1501868 and NG-1498770) using [REDACTED] [REDACTED] drug product.
4. In section 3.2.S.4.3, Document number NG-1501868 (section 2.2.4 and the table on page 16), the positive control for bile [REDACTED] did not recover in the [REDACTED]. The [REDACTED] was attributed to possible toxicity of [REDACTED] in the absence of *Vibrio cholera*. However, according to testing instructions (*point 4*) of the same document, [REDACTED] [REDACTED] supplementation. Please clarify the discrepancy.
5. Please submit a lot release protocol template for the Drug Product [Buffer, Effervescent Granule] by Monday, January 11, 2016.

Please let me know if you have any questions.

Kind Regards,
Christina

Christina Houck
Regulatory Project Manager

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