

From: Houck, Christina M
Sent: Monday, April 18, 2016 1:09 PM
To: KSmyth@paxvax.com
Subject: STN 125597/0 Information Request

Dear Kevin,

We have the following information request for **Amendment 29** under STN 125597:

1. Please revise the header throughout your Lot Release Protocol (LRP), so it is same as the LRP header you submitted in Amendment 14, which is as follows:

cc BLA Number: 125597

Lot Numbers Vaccine/Buffer:

Licensed Name of Product: Cholera Vaccine, Live, Oral

2. In the tables titled "Absence of Specified Organisms" on pages 5 and 11 of your LRP, please revise (b) (4) to the test name (b) (4)

Please respond by Monday, April 25.

Please note, the review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission. Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

Regulatory Project Manager
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review

10903 New Hampshire Avenue

White Oak Bldg. 71

Silver Spring, MD 20993

Tel: [301-796-2640](tel:301-796-2640)

Fax: [301-827-3532](tel:301-827-3532)

Email: christina.houck@fda.hhs.gov