

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125597/0.0
Review Office	OVRR
Applicant	Pax Vax Bermuda Ltd. / Lic. # 2041
Product	Cholera Vaccine Live Oral
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	24-FEB-2016 01:11 PM
Author	HOFFMAN, KELSY
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Information Request regarding the lot release protocol template
FDA Participants	Christina Houck, Goutam Sen
Applicant Participants	Kevin Smyth

Telecon Body:

From: Kevin Smyth [mailto:KSmyth@paxvax.com]

Sent: Wednesday, February 24, 2016 1:11 PM

To: Hoffman, Kelsy

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Cc: Houck, Christina M; Sen, Goutam

Subject: RE: Information Request for 125597/0 regarding the lot release protocol (lrp) template

Dear Ms. Hoffman,

Thank you for your below email which I confirm I have received.

Regards, Kevin

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From: Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]

Sent: Wednesday, February 24, 2016 10:08

To: Kevin Smyth

Cc: Houck, Christina M; Sen, Goutam

Subject: Information Request for 125597/0 regarding the lot release protocol (lrp) template

Mr. Smyth,

We have the following comments regarding your BLA 125597/0, "Cholera Vaccine, Live, Oral:"

Information Request for:

LRP BLA 125597/0 and 125597/0.4 (buffer) - Cholera Vaccine, Live, Oral

1. Please submit one combined lot release protocol (LRP) template which will cover both the vaccine and buffer.

Throughout document

2. Please ensure each test clearly states the result.

3. Please add the specification for each test.

Page 6 of 7 (Vaccine LRP); Page 10 of 14 (Buffer)

4. (b) (4)

Please use the attached template – Bioburden Tests

Page 7 of 7 (Vaccine LRP); Pages 11 of 14 – 14/14 (Buffer)

5. Absence of Specified Organisms

Please use the attached template - Specified Microbiology Tests

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.

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Bioburden Tests on xxxx

(Test Sample description: e.g. Product stage, the Harvested Control Fluids, the Harvested Virus Fluids, lot no.)

	Test Dates (start-end)	Media	Incubation Temp.	Result CFU/mL	Specification (Limit Acceptance)
Total Aerobe Count					
Yeast and Mold Count					

Specified Microbiology Tests (b) (4)

In-house

(Test Sample description: e.g. Product stage, the Harvested Control Fluids, the Harvested Virus Fluids, lot no.)

(b) (4)

Thank you and please let me know if you have any questions.

Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
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