

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	25-MAR-2016 04:38 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	Request to remove all reference to the BDS hold step of (b) (4)
FDA Participants	Kelsy Hoffman, Christina Houck, Goutam Sen
Applicant Participants	Kevin Smyth

Telecon Body:

From: Kevin Smyth [mailto:KSmyth@paxvax.com]
Sent: Friday, March 25, 2016 4:38 PM
To: Hoffman, Kelsy
Cc: Houck, Christina M; Sen, Goutam
Subject: RE: Information Request for BLA 125597

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Dear Ms. Hoffman,

Thank you for your below two emails, which PaxVax will respond to as soon as possible.

Regards, Kevin

Kevin Smyth

Vice President

Regulatory Affairs and Pharmacovigilance

PaxVax

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

Sent: Friday, March 25, 2016 12:55

To: Kevin Smyth

Cc: Houck, Christina M; Sen, Goutam

Subject: RE: Information Request for BLA 125597

Please note the following correction in red text:

2. In your amendment #19, received on March 8, 2016, you agreed to the (b) (4) hold time for BDS and withdrew from the BLA the request for the BDS hold-step duration of (b) (4) step of drug product manufacturing). We note that there are several sections in your BLA (Sections 3.2.P.3.3 (Description of Manufacturing Process and Process Controls), 3.2.P.3.4 (Controls of Critical Steps and Intermediates) and Section 3.2.P.3.5, (Process Validation and/or Evaluation) that describe the hold time as (b) (4). Please amend these sections and any other relevant sections to remove reference to the BDS hold step of (b) (4).

Kelsy F. Hoffman, Ph.D.

LCDR, USPHS

Primary Reviewer/Regulatory Project Manager

FDA/CBER/OVRR/DVRPA

10903 New Hampshire Ave.

WO71-3205

RECORD OF TELEPHONE CONVERSATION

Silver Spring, MD 20993-0002
Office- 301-796-2640
Fax- 301-595-1124

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From: Hoffman, Kelsy
Sent: Friday, March 25, 2016 3:23 PM
To: 'Kevin Smyth'
Cc: Houck, Christina M; Sen, Goutam
Subject: Information Request for BLA 125597

Mr. Smyth,

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

1. In your response to question 13a in amendment #11, received on February 26, 2016, regarding Viable Cell Count Methods, you state that "the true cell count of a positive control for the viable cell count is not possible to quantify." This would imply that the test sample also cannot be quantified, which would negate the utility of the test. However, the viable cell count method is in fact a quantitative test. The method needs to be adequately controlled such that the viable cell counts in the final vaccine are within the range shown to be safe and effective. Both underestimation and overestimation of viable counts could adversely affect the product. Please develop an appropriate positive control to allow monitoring of the assay accuracy over time. Please indicate when you will be able to implement this control into your testing.
2. In your amendment #19, received on March 8, 2016, you agreed to the (b) (4) hold time for BDS and withdrew from the BLA the request for the BDS hold-step duration of (b) (4) step of drug product manufacturing). We note that there are several sections in your BLA (Sections 3.2.P.3.3 (Description of Manufacturing Process and Process Controls), 3.2.P.3.4 (Controls of Critical Steps and Intermediates) and Section 3.2.P.3.5, (Process Validation and/or Evaluation) that describe the hold time as (b) (4). Please amend these sections and any other relevant sections to remove reference to the BDS hold step of (b) (4)

Thank you,

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Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Primary Reviewer/Regulatory Project Manager
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