

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	11-MAR-2016 02:18 PM
Author	HOFFMAN, KELS Y
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 (b) (4) acceptance criteria for equipment cleaning
FDA Participants	Kelsy Hoffman, Christina Houck, Goutam Sen
Applicant Participants	Kevin Smyth

Telecon Body:

From: Kevin Smyth [mailto:KSmyth@paxvax.com]
Sent: Friday, March 11, 2016 2:18 PM
To: Hoffman, Kelsy
Cc: Houck, Christina M; Sen, Goutam
Subject: RE: BLA 125597/0 Information Request

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Dear Ms. Hoffman,

Thank you for your below information request to which we will respond as soon as is possible.

Regards, Kevin

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

Sent: Friday, March 11, 2016 11:17

To: Kevin Smyth

Cc: Houck, Christina M; Sen, Goutam

Subject: BLA 125597/0 Information Request

Mr. Smyth,

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

In regards to the acceptance criteria for the cleaning validation of the equipment used for manufacturing of the bulk drug substance (BDS) and drug product (DP) (indicated in Table 1 of VPR-154), the (b) (4) acceptance criteria (b) (4)

(b) (4) (equipment at later steps in process). The (b) (4) acceptance criteria should be (b) (4)

(b) (4) Please indicate why the (b) (4) acceptance criteria for equipment cleaning (b) (4) of the manufacturing steps.

Please respond by March 24, 2016. Also, please let me know if you have any questions,

Thank you,
Kelsy

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