

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	01-APR-2016 11:05 AM
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	IR regarding the lot release protocol template (combined drug product and buffer)
FDA Participants	[Entered by the user, not system generated.]
Applicant Participants	[Entered by the user, not system generated.]

Telecon Body:

From: Kevin Smyth [mailto:KSmyth@paxvax.com]
Sent: Friday, April 01, 2016 11:05 AM
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 information request to which we will respond to as soon as possible.

Regards, Kevin

Kevin Smyth

Vice President

Regulatory Affairs and Pharmacovigilance

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

Sent: Friday, April 01, 2016 07:54

To: Kevin Smyth

Cc: Houck, Christina M; Sen, Goutam

Subject: Information Request for BLA 125597

Mr. Smyth,

We have the following comments regarding the lot release protocol template (combined drug product and buffer) for your BLA 125597/0, "Cholera Vaccine, Live, Oral:"

Page 1 of 10

1. Please change "Proper Name of Product" to "Trade Name".
Vaxchora is the trade name.

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2. Please remove the following (this information is only needed on page 1):

Reason for Submission: ☐ For Release
☐ For Surveillance
☐ For Licensing Action
☐ Corrected Protocol

Manufacturer Name: PaxVax, Inc.

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Manufacturer Address: (b) (4)

Proper Name of Product: Vaxchora

Label Strength:

Source Material:

Processing Method:

Manufacturer's Certification

All tests conducted on this lot are reported and pass specifications as required.

Signature: _____ Date: _____

Title: _____ Authorized Official

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4. Sachet Integrity

Please correct the specification – Inspection level II with AQL of (b) (4) Failures have defect

(b) (4) opening.

The (b) (4) opening does not match the specification submitted in 125597/0.9 submitted to CBER on 2/19/2016; which states (b) (4) opening.

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.

Thank you,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Primary Reviewer/Regulatory Project Manager
FDA/CBER/OVRR/DVRPA
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