

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

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

## Telecon Details

<b>Telecon Date/Time</b>	10-MAR-2016 11:04 AM
<b>Author</b>	HOFFMAN, KELSY
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Information Request regarding the submission of stability data for three lots using the (b) (4) working seed in the prior approval supplement
<b>FDA Participants</b>	Kelsy Hoffman, Christina Houck, Goutam Sen
<b>Applicant Participants</b>	Kevin Smyth

### Telecon Body:

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

**Sent:** Thursday, March 10, 2016 11:04 AM

**To:** Hoffman, Kelsy

## RECORD OF TELEPHONE CONVERSATION

**Cc:** Houck, Christina M; Sen, Goutam  
**Subject:** RE: BLA 125597/0 Information Request

Dear Ms. Hoffman,

Thank you for your below information request, which I confirm I have received.

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:** Thursday, March 10, 2016 07:57  
**To:** Kevin Smyth  
**Cc:** Houck, Christina M; Sen, Goutam  
**Subject:** BLA 125597/0 Information Request

Mr. Smyth,

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

With regards to your response in eCTD Sequence No. 0011 to the Information Request (IR) dated February 2, 2016:

When you submit your Prior Approval Supplement (PAS) for the (b) (4) Working Seed (WS), please include a minimum of six months of stability data for three lots each of vaccine (b) (4) final drug product produced using the (b) (4) WS.

Thank you,  
Kelsy

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

## **RECORD OF TELEPHONE CONVERSATION**

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