

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	04-FEB-2016 09:20 AM
Author	SEN, GOUTAM
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Advised to submit response to our comments to (b) (4) BDS hold time
FDA Participants	[Entered by the user, not system generated.]
Applicant Participants	[Entered by the user, not system generated.]

Telecon Body:

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From: Sen, Goutam
Sent: Thursday, February 04, 2016 1:04 PM
To: 'Kevin Smyth'
Subject: RE: STN 125597 Mid-Cycle Communication Meeting Agenda - List of PaxVax Participants and Question

Dear Kevin,

In order to address your proposal to extend the hold time of your BDS to (b) (4), we recommend you to respond to item 4 in our February 2, 2016 communication with you. We acknowledge your intention of submitting your response to this issue in March 2016 (based on your Feb. 2, 2016 email). Please note that we may not be able to comment on your responses in our Late Cycle Briefing package, which is required to be sent to you by March 18, 2016. Per PDUFA V, we are required to send you a Late Cycle Briefing package no later than 12-days before the actual Late Cycle meeting. That meeting has been scheduled for March 31, 2016.

Please let me know if you have any question.

Thank you,

Goutam

From: Kevin Smyth [<mailto:KSmyth@paxvax.com>]
Sent: Wednesday, February 03, 2016 11:35 PM
To: Houck, Christina M
Cc: Hoffman, Kelsy; Sen, Goutam
Subject: RE: STN 125597 Mid-Cycle Communication Meeting Agenda - List of PaxVax Participants and Question

Dear Ms. Houck,

Many thanks for hosting the mid-cycle teleconference today, which went very smoothly from our end of the phone.

Please find below, as requested, a list of the PaxVax participants with titles.

I also left Goutam a voicemail late in the day, to thank him for the teleconference, and to ask a general question, which is:

The mid-cycle meeting agenda did not identify “significant issues/major deficiencies” in the validation of Drug Product. In the context of the Agency’s statement in the mid-cycle agenda about potential licensure with the (b) (4) process step, does this mean that no deficiencies have been identified to-date with the DP validation done with the (b) (4) process step?

The PaxVax participants were:

Kevin Smyth, Vice President, Regulatory Affairs and Pharmacovigilance

Paul Shabram, Vice President, Technical Development

Jonathan Smith, Executive Vice President and Chief Scientific Officer

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Lisa Danzig, Vice President, Clinical Development and Medical Affairs
Grace Benedict, Associate Director, Regulatory Affairs
Violet Carvalho, Associate Director, Quality Assurance
Lawrence Chew, Director, Fermentation
Amish Patel, Director, Product Development
Fiona Cameron, Regulatory Consultant
Erlinda Quijano, Associate Director, Quality Control
Volker Niedan, Head of Quality Control
Martin Dearden, Vice President, Quality Assurance and Quality Control
Nancy Waddell, Manager, Quality Control

Regards, Kevin

Kevin Smyth

Vice President

Regulatory Affairs and Pharmacovigilance

PaxVax

900 Veterans Blvd., Ste. 500,

Redwood City, CA 94063

Office: 650.720.4585

Cell: 650.787.4406

Fax: 650.720.4585

ksmyth@PaxVax.com

www.PaxVax.com

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From: Houck, Christina M [<mailto:Christina.Houck@fda.hhs.gov>]

Sent: Monday, February 01, 2016 11:03

To: Kevin Smyth

Cc: Hoffman, Kelsy; Sen, Goutam

Subject: STN 125597 Mid-Cycle Communication Meeting Agenda

Dear Mr. Smyth,

Please see the attached agenda for our Mid-Cycle Communication Meeting scheduled for this Wednesday, February 3, 2016 at 11AM. Please use the call in information below for our meeting.

Toll free: (b) (4)

Cisco Unified Meeting Place meeting ID: (b) (4)

Kind Regards,
Christina

Christina Houck

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Regulatory Project Manager
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
10903 New Hampshire Avenue
White Oak Bldg. 71
Silver Spring, MD 20993
Tel: [301-796-2640](tel:301-796-2640)
Fax: [301-827-3532](tel:301-827-3532)
Email: christina.houck@fda.hhs.gov

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