

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	02-MAR-2016 03:44 PM
Author	SEN, GOUTAM
EDR	No
Post to Web	No
Outside Phone Number	650-787-4406
FDA Originated?	No
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Informed that CBER needs to review (b) (4) of stability data for the BDS to implement (b) (4) hold time
FDA Participants	Goutam Sen and Scott Norris
Applicant Participants	Kevin Smyth

Telecon Body: Scott Norris and I called Kevin Smyth of PaxVax to discuss their response to comment#4- bulk drug substance (BDS) stabilization hold step; communicated to them in our February 2, 2016 information request. In their response (submitted on February 26, 2016) they proposed to submit to the BLA (b) (4) of real-time stability data for three conformance lots and (b) (4) of stability data for a fourth conformance lot by March 15, 2016. They stated that (b) (4) stability data would not be available until August 2016. We informed

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Mr. Smyth that for complete evaluation of their proposed change to increase BDS hold time from (b) (4), we will need to review the complete (b) (4) of stability data. We recommended PaxVax to submit the change with all supporting data in a prior approval supplement to implement this change. PaxVax indicated that they understood CBER's position. PaxVax confirmed that they have submitted (b) (4) of stability data of drug product (DP) and BDS in the original BLA and plan to submit updated (b) (4) stability data of DP and BDS by March 15, 2016 (b) (4) hold time of their BDS). PaxVax asked about the status of their BLA review and whether any major issues identified? We informed that as of now, we have not identified any major issues with their submission. We will hold our internal late cycle meeting on March 3, 2016 and will communicate our assessment to PaxVax by March 18, 2016 in preparation of the late cycle meeting scheduled with them on March 31, 2016.