

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	31-MAR-2016 03:40 PM
Author	SEN, GOUTAM
EDR	No
Post to Web	No
Outside Phone Number	6507874406
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Discussed whether the vaccine should only be administered at the clinic setting or can it be self-administered
FDA Participants	Tina Mongeau and Goutam Sen
Applicant Participants	Kevin Smyth

Telecon Body: We called Kevin Smyth of PaxVax and enquired about PaxVax intention of administering their vaccine in clinic setting by a registered nurse/physician or the vaccine can be allowed to take home and self-administered, as their prescribing information sheet is not clear about it. PaxVax informed that their intention of administering their vaccine in clinic setting by a registered nurse/physician only. CBER requested to submit a draft language stating this information in their prescribing

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information. CBER also asked PaxVax, whether bottle water to reconstitute the vaccine will be supplied by PaxVax to the pharmacy or not. Paxvax agreed to submit a revised prescribing information sheet to their BLA addressing these two comments.