

From: Sen, Goutam
Sent: Monday, May 23, 2016 4:10 PM
To: Kevin Smyth (KSmyth@paxvax.com)
Subject: CBER comments to your Vaxchora PI, STN: 125597

Dear Kevin,

We have reviewed your May 17, 2016 submission to your STN: 125597, containing edited version of Vaxchora package insert. Please find the attached document containing our additional comments to your May 17, 2016 submitted Vaxchora PI. Please find the comment below about Indications and Usage Section revisions:

Comment to PaxVax about Indications and Usage Section Revisions:

Because Vaxchora was studied in cholera-naïve populations in pre-licensure clinical trials, the indications and usage section should specify that the vaccine is to be used in a comparable cholera naïve population. Vaxchora may not be effective in populations living in cholera-affected areas with higher pre-existing anti-vibriocidal antibodies (higher titers compared to titers in persons living in non-endemic areas). Persons living in cholera-affected areas may require a higher dosage of Vaxchora or a different dosage schedule. A single dose of Orochol at 10^9 CFU CVD 103-HgR was shown to be ineffective in a large field study conducted in Indonesia. Similar concerns were expressed by some Committee members during the 1998 Vaccines and Related Biologics Products Advisory Committee (VRBPAC) meeting.

Please submit your revised package insert as an amendment to your STN by May 27, 2016.

Thank you,

Goutam

Goutam Sen, Ph.D.

Scientific Reviewer

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