

**From:** Kevin Smyth [mailto:KSmyth@paxvax.com]  
**Sent:** Wednesday, January 06, 2016 4:36 PM  
**To:** Hoffman, Kelsy  
**Cc:** Houck, Christina M  
**Subject:** Re: BLA 125597/0 IR

Dear Ms. Hoffman.

Thank you for your below email to which we will respond as soon as is possible.

Regards, Kevin

Sent from my iPhone

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**From:** Hoffman, Kelsy  
**Sent:** Wednesday, January 06, 2016 4:07 PM  
**To:** 'Kevin Smyth'  
**Cc:** Houck, Christina M  
**Subject:** BLA 125597/0 IR

Mr. Smyth,

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

We note that you have changed the manufacturer of the working seed lots going forward. We also note that you currently have (b) (4) vials of the working seed lot manufactured by the previous manufacturer and that vials from that lot were used to manufacture the vaccine used in the clinical trials submitted in your license application. Please specify how many seed lot vials will be used per batch and per year. Please also provide a timeline of use of remaining vials (i.e., date remaining vials will be exhausted).

Thank you,  
Kelsy

Kelsy F. Hoffman, Ph.D.  
LCDR, USPHS  
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FDA/CBER/OVRR/DVRPA  
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