

From: Houck, Christina M
Sent: Tuesday, May 10, 2016 9:47 AM
To: KSmyth@paxvax.com
Cc: 'gbenedict@paxvax.com'
Subject: STN 125597/0 Post Marketing Commitment/Requirement
Importance: High

Dear Mr. Smyth,

The Post Marketing Commitment (PMC) and Post Marketing Requirement (PMR) listed below are a result of communications with you to date. We have no additional PMC's or PMR's related to your submission. We request that you submit an amendment to your BLA with your written agreement to fulfill these commitments, each of which should be stated individually.

1. Please commit to a deferred pediatric study under PREA for the treatment of disease caused by V. cholerae serogroup O1 in pediatric patients ages ≥ 2 years to < 18 years.
Final Protocol Submission: December 31, 2016

Study Completion Date: December 31, 2018

Final Report Submission: June 30, 2019

2. Please commit to establish a pregnancy registry for VAXCHORA in the US to prospectively collect data on spontaneously reported exposures to VAXCHORA occurring within 30 days prior to the last menstrual period or at any time during pregnancy. You will submit annual reports as well as a 5-year summary report, after which you will continue enrolling patients in the registry pending CBER review of the report and determination that the registry can be discontinued.
Final Protocol Submission: July 1, 2016

Study Completion: September 1, 2021

Final Report Submission: September 1, 2022

Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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