

From: Houck, Christina M
Sent: Tuesday, June 07, 2016 4:26 PM
To: KSmyth@paxvax.com
Cc: Sen, Goutam
Subject: RE: STN 125597/0 Post Marketing Requirement Edit

Dear Kevin,

My apologies. The below should have read 'Post Marketing Commitment (PMC)' not "Post Marketing Requirement". When you submit your concurrence please refer to is as a PMC.

Thank you,

Christina

From: Houck, Christina M
Sent: Tuesday, June 07, 2016 2:10 PM
To: KSmyth@paxvax.com
Cc: Sen, Goutam
Subject: STN 125597/0 Post Marketing Requirement Edit
Importance: High

Dear Kevin,

We have a minor revision to the Post Marketing Requirement PaxVax agreed to in Amendment 37 dated May 11, 2016. Please see CBER's highlighted edits below:

1. To establish a pregnancy registry for VAXCHORA in the United States to prospectively collect data on spontaneously reported exposures to VAXCHORA occurring within 28 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 and submitting annual reports pending CBER review of the reports 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

If PaxVax agrees with the minor edits, please submit an official amendment to your BLA agreeing to the commitment, as stated above. Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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Office of Vaccines Research and Review

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