

From: Thompson, Edward
Sent: Thursday, August 15, 2013 10:09 AM
To: 'Jennifer Spinella (jspinella@raretx.com)'
Cc: Lin, Xue (Mary); Kennedy, Michael
Subject: Information Request for BL 125488/0

Contacts: Jennifer Spinella

Dear Ms. Spinella:

We are reviewing your March 16, 2013 biologics license application (BLA) for Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection. We determined that the following information is necessary to continue our review:

Statistical

1. Reference your amendment dated July 15, 2013 (eCTD sequence 0014) for your response to FDA information request dated June 24, 2013: For question #7, you submitted the imputation results for the primary endpoint analysis. Please submit your SAS code for this analysis so that the results can be reproduced.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by August 29, 2013 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is March 18, 2014.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me at (301) 827-9167.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB

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