

From: Thompson, Edward
Sent: Thursday, August 22, 2013 8:51 AM
To: 'Jennifer Spinella (jspinella@raretx.com)'
Cc: Zhong, Lilin; 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:

1. For all four viruses (b) (4), please provide the following:
 - a. A detail description of the scale-down model of your viral clearance study. Please indicate the critical parameters in comparing to those used for the manufacturing scale.
 - b. Additional information on the test article used for your viral clearance studies, including the date of manufacturing, the specific steps the test articles were taken.

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 September 5, 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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