

**From:** Thompson, Edward  
**Sent:** Thursday, March 28, 2013 4:36 PM  
**To:** 'Jennifer Spinella (jspinella@raretx.com)'  
**Cc:** Goud, Ravi; Kennedy, Michael; Mahmood, Iftekhhar  
**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')<sub>2</sub> (Equine) Injection. We determined that the following information is necessary to continue our review:

1. Please submit a detailed pharmacovigilance plan (PVP) in accordance with the ICH E2E Pharmacovigilance Planning Guidance at the following link:  
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm129411.htm>
2. The major components of the pharmacovigilance plan are: (a) the product safety specification, and (b) the risk management plan that outlines the important identified risks, important potential risks, and important missing information. The risk management plan should detail the specific action plans to address each of these concerns after licensure. The PVP is developed by the sponsor, and FDA will evaluate its adequacy in conjunction with all other elements of the biologics license application.

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 April 11, 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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