

From: Thompson, Edward
Sent: Friday, August 23, 2013 8:40 AM
To: 'Jennifer Spinella (jspinella@raretx.com)'
Cc: Goud, Ravi; 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. Request that the sponsor provide a product insert in English for Antivipmyn to confirm similarity in dosing to Anavip.
2. In section 5.4.4 of the integrated summary of safety report there is a review of immune system disorders. Please provide the rate of these cases that occur in the Anavip/Anavip, Anavip/Placebo, the CroFab/CroFab arms, as well as the rate for all patients who received Anavip (both arms together).

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 6, 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