

From: Thompson, Edward
Sent: Tuesday, February 25, 2014 8:50 AM
To: 'Jennifer Spinella (jspinella@raretx.com)'
Cc: 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 request that you make the following postmarketing commitments:

1. Instituto Bioclon, S.A. de C.V. (Bioclon) commits to (b) (4) [REDACTED] and the final study reports will be submitted as a BLA supplement within 3 months of completion of the studies.
2. Bioclon commits to provide the test method standard operating procedures (SOPs), validation protocols, and validation study reports (including all test results) for the detection of cytopathogenic and/or hemadsorbing agents (as described in 9 CFR 113.46) and the detection of extraneous viruses by the fluorescent antibody technique (as described in 9 CFR 113.47) as a BLA supplement within one year after approval.
3. Bioclon commits to (b) (4) [REDACTED] and the final study report will be submitted as a BLA supplement within 3 months of completion of the study.
4. Bioclon commits to perform a study to evaluate (b) (4) [REDACTED] and to perform bioburden and endotoxin (b) (4) [REDACTED]. Final testing (b) (4) [REDACTED] will be done and the results will be compared with the product manufactured using the (b) (4) [REDACTED]. The final study report will be submitted within one year after approval.
5. Bioclon commits to complete the validations of (b) (4) [REDACTED] and to provide the final validation report to CBER by April 30, 2014.
6. Bioclon commits to provide the (b) (4) [REDACTED] and the final study report will be submitted as a BLA supplement within 3 months of completion of the study.

7. Bioclon commits to provide stability updates for the conformance lots (b) (4) (a lot initiated during the pre-licensure inspection) annually as a PMC Annual Report. The final stability report will be submitted as a PMC Final Study Report within 3 months of the final time point.
8. Bioclon commits to submitting interim stability results for each conformance lot as PMC updates within 4 weeks after QC review/approval.
9. Bioclon commits to place the next three bulk lots on full stability study with at least the following parameters being monitored: (b) (4) by using the validated method (code PVM-ID-013). The final study report will be submitted within 3 months after completion of the study.

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 for this information request as an amendment to this file by February 27, 2014 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.

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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