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Bioclon SA de CV Instituto
Information Request: STN 125335/0
February 6, 2009

The Center for Biologics Evaluation and Research is continuing to review your biologics license application for Centruroides (Scorpion) Immune F(ab)2 Intravenous (Equine) submitted on January 21, 2009. We are sending you our second information request of the day. Please provide the following:

Pharm/Tox

1. Please indicate if and how Antivipmyn used in the acute toxicity study in rats (Study number 1299-001, Appendix A) differs from Anavip.

CMC

2. Please forward a certificate of analysis, release specifications, and a manufacturing flowchart with narrative for Anavip.

Pharmacokinetics

3. Please provide Alacramyn pharmacokinetic study data described in the 2005 Toxicon paper in an excel worksheet. The data should include subjects' age, weight, dose, gender, plasma concentrations vs time data, individual PK parameters derived from plasma concentrations vs time data.

Clinical

4. To facilitate reviewing the submission, please submit electronic files in Microsoft Word for Sections 1 to 13 of the following clinical study reports: XE-C-01, XE-C-02, XE-C-03, XE-C-04. For XE-C-05, please submit the entire report not including appendices. Please also submit in Microsoft Word sections 1.0 to 8.0 of the Integrated Summary of Efficacy Report (XE-ISE-007) and sections 1.0 to 14.0 of the Integrated Summary of Safety Report (XE-ISS-06).

5. The electronic case report tabulation datafiles are currently unclear. For each study, please provide an adobe acrobat file defining each variable, including the codes for those variables in which codes are used. The dates and times should not be presented as 4- or 5-digit numbers, but as actual dates and times.

6. The Adverse Event datafiles should include columns relating to (a) infusion start time, (b) infusion end time, (c) whether event is between start time and within 48 hours of end of the infusion, and (d) whether event is between start time and within 72 hours of end of the infusion.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review the annual report. You are requested to submit the above information as an amendment to this file no later than February 20, 2008. If you are unable to respond by this date, please contact the Agency to discuss an alternate response date.

Thank you for your assistance,

Debbie Cordaro
Regulatory Project Manager
FDA/CBER/DBA/OBRR/RPMB

Information provided by: RF and HSK Date: 2/6/09

Approved by _____ Date _____ Transmitted by DLC Date 2/6/09

Number of pages (including cover sheet) _2____