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To: ----------(b)(4)------
Bioclon SA de CV Instituto
Information Request: STN 125335/0
March 12, 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 have the following requests:

1. Please submit the PK report for your investigation published in *Toxicon* (volume 46 pp797-805, 2005) in a clinical study format, and include the study documents such as protocol, investigator, IRB and consent information, as well as details of analytical methods for study samples, and safety data.

2. For Study AL-03/07, please submit
   - an interim clinical study report covering the period between August 2005 and June 2008, and including data listings to June 2008 in an updated Section 16.2, and
   - a pdf file with definitions for the parameters and coding for the study dataset.

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 this information as an amendment to this file no later than March 18, 2009. Please do not send an advance copy of the response by email unless requested to do so by FDA. If you anticipate you will not be able to respond by this date, please contact the Agency immediately. The action due date for this file is July 24, 2009.

Thank you for your assistance,

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

Information provided by IM & HSK Date: 3/12/09 Transmitted by DLC Date 3/11/09 6

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