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To: -----(b)(4)-----
Information Request: STN 125335/0
April 21, 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 request for additional information:

1. Please submit your toxicity assessment for borates contained in the final formulation of Anascorp.

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 April 29, 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[Reviewer Initials]_ Date ES/_____ Transmitted byDLC __ Date 4/21/09

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