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Information Request: STN 125335/0
April 17, 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:

Please submit the case report forms for the 15 subjects enrolled in the controlled trial AL-02/03. We are requesting that these be provided in .pdf format only.

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 22, 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: HSK 4/17/09_____ Transmitted byDLC __ Date 4/17/09

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Thank you.

Number of pages (including cover sheet) _1____