



**FACSIMILE TRANSMISSION RECORD**  
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Bioclon SA de CV Instituto  
Information Request: STN 125335/0  
February 24, 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 reviewed your February 20, 2009 amendment responding to our fax of February 6, 2009 (received at 14:34) and you are requested to provide the following additional information:

1. Please clarify if the new electronic data files for AL02/03 and AL03/06 overlap with old ones previously submitted in January?
2. Please explain why the data files for AL02/04, 05, 06 or AL99/02 were not submitted?  
These studies cannot be properly reviewed without data files.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission. You are requested to submit the above information as an amendment to this file no later than March 3, 2009. If you are unable to respond by this date, please contact the Agency to discuss an alternate response date. 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: HSK Date: 2/24/2009

Approved by \_\_\_\_\_ Date \_\_\_\_\_ Transmitted by DLC Date 2/24/09

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Thank you.

Number of pages (including cover sheet) \_1\_