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Bioclon SA de CV Instituto
Information Request: STN 125335/0
February 26, 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 clarification:

Please provide a breakdown of the subject distribution for the following study:

AL-03/07 – Treatment Protocol for use of Anascorp in patients with Scorpion Sting Envenomation in Arizona, US.

There are a total of 22 centers/clinics/hospitals, etc throughout Arizona that are listed as participating in this study. Please identify how many subjects were enrolled and treated at each of the 22 participating sites; i.e.:

- Site #1 Dr. Duane Crist, Banner Baywood Medical Center, Mesa AZ, how many subjects enrolled/treated
- Site #2 Dr. Trina Bogart, Banner Thunderbird Medical Center, Glendale, AZ, how many subjects enrolled/treated,
- Etc, for all 22 sites

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 contact me by email or fax with is information no later than COB tomorrow, February 27, 2009. If you are unable to respond by this date, please contact the Agency. 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: RW Date: 2/26/2009 Transmitted by: DLC Date 2/26/09 6
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