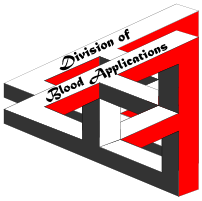

FACSIMILE TRANSMISSION RECORD
Division of Blood Applications
1401 Rockville Pike, Suite 400N, HFM-380
Rockville, Maryland 20852-1448

FAX (301) 827-2857
TEL (301) 827-3524

To: -----(b)(4)-------
Bioclon SA de CV Instituto
Information Request: STN 125335/0
March 11, 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:

When a new product is marketed, the exposed population may differ from the population studied in pre-approval trials. The exposed subjects in pre-approval trials for Anascorp are limited in number and may not include the variety of types of patients who will likely be exposed to the product after licensure. Pharmacovigilance plans are designed to identify and describe potential serious safety risks, important missing information, or inadequately studied at-risk populations, and should include routine pharmacovigilance (i.e., compliance with applicable postmarket reporting requirements under FDA regulations) and possibly additional post-market safety monitoring activities.

The ICH E2E Pharmacovigilance Planning (PVP) guidance http://www.fda.gov/cber/gdlns/ichpvp.htm) indicates that for products with important identified risks, important potential risks, or important missing information, additional actions designed to address these concerns should be considered as part of a pharmacovigilance plan. The pharmacovigilance plan is developed by a product's sponsor and is specifically focused on detecting new safety risks and/or evaluating already identified safety risks.

Please submit a detailed pharmacovigilance plan in accordance with the E2E PVP guidance.

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 8, 2009. 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:AO Date: 3/10/09 _____ Transmitted by DLC Date 3/11/09 6

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