



Mid-Cycle Communication
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Application: BL STN 125488/0, Original BLA
Product: Crotalidae Immune Fab2 Equine Intravenous
Proposed Indication: Management of patients with pit viper envenomation and prevention of late or recurrent coagulopathies
Applicant: Instituto Bioclon S.A. de C.V.
Chair: Michael Kennedy, PhD, CBER/OBRR/DH/LPD
RPM: Edward Thompson, CBER/OBRR
Meeting: Wednesday, September 4, 2013, 1:30 – 2:00 p.m.

FDA Attendees:

Michael Kennedy, PhD, CBER/OBRR/DH/LPD
Edward Thompson, CBER/OBRR
Betsy Jett, CBER/OBRR

Instituto Bioclon Attendees:

Jennifer Spinella, MT (ASCP), RAC, VP Regulatory Affairs and Quality Assurance, Rare Disease Therapeutics, Inc
Tomas Gonzalez, MS, MBA/TM, Director, Regulatory Affairs, Rare Disease Therapeutics, Inc
Jude McNally, RPh, DABAT, VP, Medical Science Liaison, Rare Disease Therapeutics, Inc
Walter Garcia, MD, Medical Director, Instituto Bioclon
Rita Mancilla, Plant Manager, Instituto Bioclon
Alexandra Sanchez, Drug Safety Coordinator, CCRP, Instituto Bioclon

Discussion Summary

1. Any significant issues identified by the review committee to date:

Some issues were identified with the clinical data that are still under review.

2. Information regarding major safety concerns:

Currently reviewing open issues regarding cresol levels and awaiting Applicant's response to the information request sent on August 22, 2013.

3. Preliminary review committee thinking regarding risk management:

No issues have been identified to date during the on-going review of Pharmacovigilance Plan version 1.0.

4. Any information requests sent and not received:

None

5. Any new information requests to be communicated:

None

6. Proposed date for the late-cycle meeting:

November 21, 2013 at 2:00 pm EDT

7. Updates regarding plans for the AC meeting:

Tentatively, there are no plans for advisory committee meeting.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates :

External Late-Cycle Meeting Nov 21, 2013

Send FDA Action Letter Mar 18, 2014

End