

1st Committee Meeting for STN 125488/0

Instituto Bioclon S.A. de C.V.

Crotalidae Immune Fab2 Equine

Original BLA

Date and Time: April 4, 2013 at 11:00 am

Location: Woodmont Office I, Room 583N

Meeting Chairperson: Howard Chazin, MD, Deputy Director, MBA, OBRR/DH

Application Chairperson: Michael Kennedy, PhD, OBRR/DH/LPD

Clinical Reviewer: Mitchell Frost, MD, OBRR/DH/CRB

Clinical Pharmacology Reviewer: Iftekhar Mahmood, PhD, OBRR/DH

Pharmacology/Toxicology Reviewer: Evi Struble, PhD, OBRR/DH/LPD

CMC Reviewers: Robert Fisher, PhD, OBRR/DH/LPD

Maria Luisa Virata, PhD, OBRR/DH/LPD

Yonggang Wang, PhD, OBRR/DH/LPD

Lilin Zhong, OBRR/DH/LPD

DMPQ Reviewer: Nancy Waites, DMPQ/OCBQ

Statistical Reviewer: Mary (Xue) Lin, PhD, OBE/DB

Epidemiologist Reviewer: Ravi Goud, MD, OMPT/CBER/OBE/DE/AEB

APLB Reviewer: Michael Brony, PharmD, OMPT/CBER/OCBQ/DCM/APLB

BIMO Reviewer: Erin McDowell, OMPT/CBER/OCBQ/DIS/BMB

Lot Release: Erica Giordano, OMPT/CBER/OCBQ/DMPQ/PRB

DSBQC Reviewer: Karen Campbell, OMPT/CBER/OCBQ/DBSQC/QAB

RPM: Edward Thompson, OBRR/DBA/RPMB

Meeting attendees:

Mahmood Farshid, PhD, Deputy Director, OBRR/DH

Alan Williams, PhD, Deputy Director, OBRR/DBA

Nisha Jain, MD, Chief, OBRR/DH/CRB

Betsy Jett, OBRR/DBA

Iliana Valencia, Chief, OBRR/DBA/RPMB

Mark Shields, OBRR/DBA/RPMB

Dorothy Scott, MD, Chief, OBRR/DH/LPD

Renee Rees, PhD, OBE/DB

Boguang Zhen, PhD, Chief, OBE/DB/TEB

Carolyn Renshaw, Chief, OCBQ/DMPQ/BI

Short Summary: Management of patients with pit viper envenomation and prevention of late or recurrent coagulopathies

Reference IND 11275

PreBLA Meeting: May 8, 2012, CRMTS #8411

Meeting discussion:

- Ensure the submission is complete.

CMC Reviewer indicated the process validation is missing. Other CMC information are missing from the application to include depyrogenation tunnel and qualification of the filling line. The OBE reviewer indicated that the pharmacovigilance plan is missing. An information request was sent on March 28, 2013.

- Ensure a reviewer is assigned to review each section of the application.

All reviewers confirmed and assigned as appropriate by the application chairperson.

- Determine if inspections are necessary for GMP pre-license or pre-approval, GLP for studies performed under the Animal Rule, and identify BiMo inspection sites.

The inspection of the facilities in Mexico depends on the State department approval to allow federal officials to travel in the area. If inspectors are not allowed in the area, then this application would be issued a Complete Response letter.

- Determine if advisory committee meeting is required. If not, then a justification is required in this meeting summary (per Section 918)

An advisory committee meeting is not needed as there is nothing unusual in the product's manufacture, indication, or mode of action, that would require input from an AC. The application is possibly on a path for refuse to file (RTF).

- Notify PeRC if PREA is triggered

Orphan drug status

- Confirm the review schedule and all future meeting dates.

Schedule reviewed and the pending RTF status. RPM indicated that the RTF letter ready comments are due on May 2, 2013 (day 45). The RTF letter is due 14 days later.

- Identify if consult reviewers are needed in the review process.

A consult Veterinarian for the horse studies to include viral testing.

- Identify any potential issues and confirm adequacy of the data sets.

The data sets submitted electronically thru the gateway are adequate for the application review

- Identify follow up activities to be completed before the next meeting (Filing Meeting).

Letter-ready comments for the RTF letter to the applicant

Prepare an internal meeting for CRB and OBE statistical group.

Prepared by: Edward Thompson

Reviewed/Revised: Michael Kennedy