

Filing Meeting

Subject: STN: 125488/0

Product: Crotalidae Immune Fab2 Equine Injection

Applicant: Instituto Bioclon S.A. de C.V.

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

Location: CBER Conf. WOC 1 583

Start: Thu 5/2/2013 12:00 PM

End: Thu 5/2/2013 12:45 PM

Attendees:

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| Meeting Chairperson: | Basil Golding |
| Application Chairperson: | Michael Kennedy |
| Branch Chiefs and Reviewers: | Fisher, Robert; Giordano, Erica; Goud, Ravi; Lin, Xue (Mary); Mahmood, Iftekhar; Mcdowell, Erin; Struble, Evi; Virata, Maria Luisa; Waites, Nancy; Wang, Yonggang; Zhong, Lilin; Frost, Mitchell M; Campbell, Karen M; Dennis, John; Rees, Renee; Zhen, Boguangjhn; Jain, Nisha; Renshaw, Carolyn; Scott, Dorothy; Shields, Mark; |

Agenda: Filing meeting to discuss relevant content of the application and present an overview of the filing status

Discussion:

1. Identify Refuse to File (RTF) issues or if a Deficiencies Identified letter is required.

All reviewers signified that this application may be filed and no deficiencies identified for the filing letter.

2. Identify any required material that may have been omitted from the submission.

None identified.

3. Identify any substantive deficiencies or issues that may potentially have significant impact on your ability to complete this review or approve the application.

None noted.

4. Obtain comments from you regarding whether this submission can be filed.

See item #1

5. APLB reviewer comments on existence of a Proprietary Name Review.

APLB has all that is needed to perform a proprietary name review. The PNR amendment was submitted on March 28, 2013.

6. Propose the product would be subject to Lot Release Surveillance or Exempt from Lot Release.

DSBQC propose that the product would be subject to lot release and they will need a lot release protocol template

Prepared: Edward Thompson

Revised: Michael Kennedy