

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: STN 125488/0 Office: OBRR  
Title/Product: Crotalidae Immune F(ab)'<sub>2</sub> (Equine)  
Sponsor/Applicant: Instituto Bioclon S.A. de C.V. (Bioclon)  
Telecon Date/Time: May 5, 2015 at 12:45 p.m. Initiated by FDA? Yes

Communication Category: ADVICE (AD)

Drafted: Edward Thompson  
Revised: Iftekhar Mahmood

Telecon Summary: Discuss PK Parameter Calculations

FDA Participants:

Edward Thompson, RPM, OBRR/RPMS  
Iftekhar Mahmood, PhD, OBRR/DHCR

Non-FDA Participants:

Participants from Bioclon

- Walter Garcia
- Refugio Rivera
- Javier Pérez

Participants from Rare Disease Therapeutics, Inc. (RDT)

- Michelle Taylor
- Milton Ellis
- Jude McNally
- Tomas Gonzalez

Telecon Body:

This teleconference was requested by Dr. Iftekhar Mahmood to obtain information regarding pharmacokinetic (PK) data analysis as well as the dose used in the estimation of PK parameters.

FDA asked about the PK dose used in the PK study. Bioclon responded that 1 vial of 1.86 % was used.  $1.86\% = 81.8 \text{ mg}$ . However, this dose was not used in the estimation of PK parameters and the sponsor could not respond about the exact dose used in the PK analysis submitted to the BLA.

FDA requested that Bioclon recalculate the PK parameters based on 81.86 mg dose. The parameters the sponsor needs to calculate are clearance, volume of distribution at steady state and volume of distribution of the central compartment.

Bioclon agreed to provide this data immediately to the application today.