



Our STN: BL 125488/0

RESUBMISSION ACKNOWLEDGEMENT

Instituto Bioclon, S.A. de C.V.
Attention: Walter Garcia Ubbelohde, MD
Instituto Bioclon
Amores 1304
Colonia del Valle, Distrito Federal
Mexico

Dear Dr. Garcia Ubbelohde:

We have received your March 6, 2015 resubmission to your biologics license application for Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection on March 6, 2015.

The resubmission provides additional information on the cleaning validation for the filling equipment at your (b) (4) Mexico facility outlined in the Complete Response Letter issued on March 18, 2014 that you submitted in response to our March 18, 2014 complete response letter.

We consider this a complete, class 1 response to our action letter. Therefore, the user fee goal date is May 6, 2015.

If you have any questions, please contact the Regulatory Project Manager, Edward M. Thompson, at (240) 402-8443.

Sincerely yours,

Ilana Valencia, MS
Chief, Regulatory Project
Management Staff
Office of Blood Research and Review
Center for Biologics
Evaluation and Research