



Our STN: BL 125488/0

Instituto Bioclon, S.A. de C.V.
Attention: Ms. Jennifer Spinella
Rare Disease Therapeutics, Inc.
9550 Cuyamaca Street, Suite 203
Santee, CA 92071

Dear Ms. Spinella:

We have reviewed your submission dated March 16, 2013 to your biologics license application (BLA) for Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection, requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, ANAVIP, is acceptable at this time.

We will perform another proprietary name review of ANAVIP closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

If you have any questions, please contact Edward Thompson at (301) 827-9167.

Sincerely yours,

Basil Golding, MD
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research