

Memorandum

**Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Manufacturing and Product Quality**

To: STN 125488/0 Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection; Anavip
From: Nancy Waites, OCBQ/DMPQBI/ HFM-675
Through: Carolyn Renshaw, Branch Chief, OCBQ/DMPQBI/ HFM-675
Subject: Categorical Exclusion under 21 CFR §25.31(c)

I have reviewed pertinent sections of the Biologics License Application (STN number 125488/0) from Instituto Bioclon, S.A. de C.V. to obtain approval for the manufacture of Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection; Anavip, and find that their request for a categorical exclusion from an environmental assessment under 21 CFR 25.31(c) is justified since the substances occur naturally in the environment and the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. To Instituto Bioclon's knowledge, no extraordinary circumstances exist that modify this exclusion.

Concurrence:

_____ Date _____

John A. Eltermann, Jr., R.Ph., M.S.
Director
Division of Manufacturing Product Quality