Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	8900.01
True Name	Crotalus Atrox Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Red Rock Biologics
Date of Compilation Summary	June 04, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Three doses were given one month apart
Study Animals	Horses
Challenge Description	Not Applicable
Interval observed after challenge	30 minutes post vaccination, daily for 2 days, and weekly thereafter
Results	

State	Clinic	Horses With Any Reaction	Reactions After 1st Vaccination	Reactions After 2nd Vaccination	Reactions After 3rd Vaccination
AZ		5/163 = 3%	3/163=2%	3/163=2%	1/163=<1%
CO		0/29=0%	0/29=0%	0/29=0%	0/29=0%
OK		5/42=12%	3/42=7%	2/42=5%	2/42=5%
CA	Site A	1/8=13%	0/8=0%	1/8=13%	1/8=13%
	Site B	2/6=33%	1/6=17%	0/6=0%	1/6=17%
	Site C	0/31=0%	0/31=0%	0/31=0%	0/31=0%
	Site D	5/15=33%	5/15=33%	4/15=27%	3/15=20%
		19/70=27%	12/70=16%	4/70=6%	12/70=16%
	Total	**27/130=21%**	**18/130=14%**	**9/130=7%**	**17/130=13%**
Tx	Site A	1/28=4%	1/28=4%	0/28=0%	0/28=0%
	Site B	1/272=<1%	1/272=<1%	0/272=0%	0/272=0%
	Total	**2/300=1%**	**2/300=<1%**	**0/300=0%**	**0/300=0%**
All	**Total**	**39/664=6%**	**26/664=4%**	**14/664=2%**	**20/664=3%**

Reaction rates in the study:

39 horses (6%) had some type of abnormality. 37 had injection site reactions, while 2 had systemic reactions; (1 horse had Diarrhea at 72 hours, and 1 horse had sore front feet at 24 hours). Both systemic reactions were resolved within 1 day. All of the injection site reactions were resolved within 3 weeks (with most resolved by 2 weeks).

USDA Approval Date	5/21/2010