

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	4865.22
True Name	Encephalomyelitis Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vetera VEWT - No distributor specified
Date of Compilation Summary	February 06, 2019

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	Efficacy
Pertaining to	Clostridium tetanus
Study Purpose	Demonstration of efficacy against Clostridium tetanus
Product Administration	One dose, administered intramuscularly
Study Animals	10 guinea pigs (10 vaccinates)
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	Vaccinate serum samples were collected and pooled, then tested for antitoxin content by indirect Enzyme-Linked Immunosorbent Assay. A satisfactory value which met the requirements per 9 CFR 113.114(c) was achieved.
USDA Approval Date	May 1, 2008

Study Type	Efficacy
Pertaining to	Eastern equine encephalomyelitis
Study Purpose	Demonstration of efficacy against Eastern equine
	encephalomyelitis
Product Administration	Two doses, administered intramuscularly, 14 to 21 days apart
Study Animals	12 guinea pigs (10 vaccinates, 2 controls)
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	Serum samples were tested by a plaque reduction, serum neutralization test, 14 to 21 days after the second injection. Vaccinates and controls were evaluated in terms of Eastern equine encephalomyelitis per the criteria in 9 CFR 113.207(b) and the requirements were met.
USDA Approval Date	May 1, 2008

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Study Type	Efficacy
Pertaining to	Venezuelan equine encephalomyelitis
Study Purpose	Demonstration of efficacy against Venezuelan Equine
	Encephalomyelitis
Product Administration	Two doses, administered intramuscularly, 14 to 21 days apart
Study Animals	12 guinea pigs (10 vaccinates, 2 controls)
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	Serum samples were tested by a plaque reduction, serum neutralization test, 14 to 21 days after the second injection. Vaccinates and controls were evaluated in terms of Venezuelan equine encephalomyelitis per the criteria in 9 CFR 113.207(b) and the requirements were met.
USDA Approval Date	May 1, 2008

Study Type	Efficacy
Pertaining to	Western equine encephalomyelitis
Study Purpose	Demonstration of efficacy against Western equine
	encephalomyelitis
Product Administration	Two doses, administered intramuscularly, 14 to 21 days apart
Study Animals	12 guinea pigs (10 vaccinates, 2 controls)
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	Serum samples were tested by a plaque reduction, serum neutralization test, 14 to 21 days after the second injection. Vaccinates and controls were evaluated in terms of Western equine encephalomyelitis per the criteria in 9 CFR 113.207(b) and the requirements were met.
USDA Approval Date	May 1, 2008

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety in pregnant mares under field conditions at
	two different test sites
Product	Two intramuscular doses, given 16-28 days apart. 54 pregnant mares
Administration	were injected with placebo and 325 pregnant mares were vaccinated
	with test product.
Study Animals	Three hundred seventy-nine pregnant mares at two locations were
	included in the study. The mares were confirmed to be pregnant by
	serum hormonal evaluation on the day of the first vaccination.
Challenge	Not applicable
Description	
Interval observed	1 st and 2 nd trimester: Mares observed immediately after vaccination
after vaccination	and daily for overall health and for abortion. Resulting foals were
	observed daily for 7 days following birth.
	3 rd trimester: Mares observed immediately after vaccination and
	daily for overall health and for abortion. Resulting foals were
	observed daily for 30 days following birth.
Results	Results shown on next page

Results	Study 2013 North Dake							
	Group	Vaccin		Confirm Pregnant		Foals		Parturition Rate
	1 st trimester product	:/ 143		127		114		90%
	1st trimeste placebo	r/ 59		54		49	9	91%
	2 nd trimeste product	r/ 6	,	6		6		100%
	3 rd trimester product	r/ 140		117		117		100%
	Total – all animals	348		304		286	9	94%
	Total – product on	289		250		237	9	95%
	Total – placebo on	59		54		49	9	91%
	Study 2013 Misssouri S	-PM-1009				_		
	Group	Vaccin		Confirme Pregnant	I E	Foals		arturition ate
	2011 3 rd trimester	5	5		5	5	_	00%
	2012 1 st trimester	1	1		1	-	10	00%
	2012 2 nd trimester	53	4	3	3	89	91	%
	2012 3 rd trimester	26	2	6	2	25	96	5%
	Total – product	85	7	5	7	/0	93	5%
	Study 2014 North Daka		·					
		Vaccinated	Confirm Pregnan		aled	Parturit Rate	ion	Foals Survived to End of Observation Period
	2 nd trimester	52	52	52		100%		51*
	vaccinated 3 rd trimester vaccinated	69	69	67*	**	97.1%		67
	*Lost foal af **One mare cooperator.	*Lost foal affirmed by study cooperator to be due to causes other than vaccination. **One mare died due to causes other than vaccination, as affirmed by study						
	All other 10a	is were normal	i anu nealt	пу				

	<u>s 5 mont</u> ion, until es. Two fo ted to vac	hs of age	
Product Administration Two doses, administered intramuscularly approximately 3 – Administration Study Animals 880 horses, including 218 foals 3 months of age and 52 foals Challenge Description Not applicable Interval observed after challenge Not applicable Results Horses were observed at least daily following each vaccinati resolution of any observed reactions. There were no systemic reactions observed at any of the site one horse died from causes affirmed by licensee not attribute Adverse events were limited to transient, non-painful swellin site that resolved without treatment. Local injection site reactions are summarized below across t Site Total Number Of Vaccinates Mith Transient Injection Site Swelling After 1 st 2 nd	<u>s 5 mont</u> ion, until es. Two fo ted to vac	hs of age	
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dose dose	dose	2 nd dose	
North Dakota37837840	374	378	
California 43 43 4 3	39	40	
Missouri 292 290 0 0	292	290	
Texas 170 169 6 1	164	168	
Total 883 880 14 (1.6%) 4 (0.5%) 6	869 (98.4%)	876 (99.5%)	

Summary	Number Of	Number Of Vaccinates	Transient	tes With t Injection welling	Number Of Normal Vaccinates	
Age	Vaccinates	Administered 2 doses	After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose
2-4 months	179	179	0	0	179	179
5-7 months	0	0	n/a	n/a	n/a	n/a
8-11 months	0	0	n/a	n/a	n/a	n/a
1-5 years*	121	121	2	0	119	121
6-15 years*	78	78	2	0	76	78
>16 years	0	0	n/a	n/a	n/a	n/a
Total	378	378	4	0	374	378

*Swellings were 3cm in size observed 1-3 days post vaccination that resolved within 3 days.

California Site:

Summary	Number Of Vaccinates	Number Of Vaccinates Administered	Vaccinates With Transient Injection Site Swelling		Number Of Normal Vaccinates	
Age		2 doses	After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose
2-4 months*	7	7	0	2	7	5
5-7 months**	1	1	1	0	0	1
8-11 months	0	0	n/a	n/a	n/a	n/a
1-5 years***	19	19	2	0	17	19
6-15 years****	15	15	1	1	14	14
>16 years	1	1	0	0	1	1
Total	43	43	4	3	39	40

*Swellings were 3cm in size observed within hours post vaccination that resolved within several hours. **Swelling was 3cm in size observed immediately post vaccination that resolved within several hours. ***1 horse had a swelling 1cm in size observed immediately post vaccination that resolved within several hours. 1 horse had a swelling observed on day 1 that increased in size to 9cm on day 3 post vaccination and resolved by day 5.

****Same horse had a swelling after each vaccination that resolved within 3 weeks. Size after the first vaccination was 24cm. Size after the second vaccination was 10cm.

Missouri Site: Summary	Number Of Vaccinates	Site Swelling			Number Of Normal Vaccinates		
Age	vaccinates	2 doses	After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose	
2-4 months	33	32	0	0	33	32	
5-7 months	0	0	n/a	n/a	n/a	n/a	
8-11 months	0	0	n/a	n/a	n/a	n/a	
1-5 years	225	224	0	0	225	224	
6-15 years	32	32	0	0	32	32	
>16 years	2	2	0	0	2	2	
Total	292	290	0	0	292	290	

Texas Site:

Summary	Number Of Vaccinates	Number Of Vaccinates Administered	Vaccinates With Transient Injection Site Swelling		Number Of Normal Vaccinates		
Age	vaccinates	2 doses	After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose	
2-4 months	0	0	n/a	n/a	n/a	n/a	
5-7 months	52	51	1	1	51	50	
8-11 months	0	0	n/a	n/a	n/a	n/a	
1-5 years	114	114	5	0	109	114	
6-15 years	0	0	n/a	n/a	n/a	n/a	
>16 years	4	4	0	0	4	4	
Total	170	169	6*	1**	164	168	
		bserved 4-7 days day post vaccinat				n 6 days.	

USDA	November 1, 2010
Approval Date	