

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1995.20
True Name	West Nile Virus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Equi-Jec WNV - No distributor specified Vetera WNV - Boehringer Ingelheim (Canada) Ltd. Vetera WNV - No distributor specified
Date of Compilation Summary	February 04, 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	West Nile Virus (WNV)			
Study Purpose	Demonstration of twelve me	onth duration of i	immunity agains	t disease
	True deces a desinistant dista			
Product Administration	Two doses, administered intr	amuscularly, 25 da	iys apart	
Study Animals	30 horses (20 vaccinates, 10	placebo controls) 4	1-5 months of age	e
Challenge Description	West Nile Virus was admin	istered at 380 day	ys (10 vaccinat	ed and 5
	placebo control animals) or	: 408 days (10 v	accinated and 5	placebo
	control animals) post-final va	accination.		
Interval observed after	Horses were observed twic	e daily for 14 day	ys post-challeng	ge and
challenge	once daily for an additiona	l 7 days post-cha	llenge.	-
Results	An animal was considered	affected by chall	lenge if it devel	oped
	neurological disease, as me	easured by morta	lity and microso	copic
	evidence of virus-induced	brain disease (his	stopathology).	-
			1 007	
	Animals were also monitor	red for viremia (d	letection of WN	IV in
	the blood).	,		
	,			
	Results are summarized as	follows:		
	Outcome	Controls	Vaccinates	
	Mortality	7/10 (70%)	1/20 (5%)	-
	Viremia at least one day	10/10 (100%)	2/20 (10%)	
		- (/ • /	- (- · •)	J
	See raw data on following	nages		
		pages.		
USDA Approval Date	September 3, 2010			

Treatment	#	Died or Euthanized due	Severity Histopa	thological lesions
Treatment # Treatment # 1 2 3 4 2 3 4 5 (10 horses) 6 7 8 9 10 10 1 2 3 4 5 6 7 8 9 10 10 1 2 3 4 5 6 7 8 9 Vaccinates 10 (20 horses) 11 12 13 14 15 16 17		to disease severity	Medulla	Pons
	1	Yes	3	3
	2	Yes	3	3
	3	Yes	3	3
	4	Yes	3	3
Controls	5	Yes	3	3
(10 horses)	Treatment # Eu 1 2 3 4 2 3 4 5 5 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 Vaccinates 10 (20 horses) 11 12 13 13 14 15 16 17 18 19 19	Yes	2	2
		Yes	1	1
	8	No	1	1
	9	No	1	1
	10	No	1	0.5
	1	Yes	3	3
	2	No	2	0.5
	3	No	1	1
	4	No	1	0.5
	5	No	1	0.5
	reatment # 1 2 3 4 2 3 4 5 0 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 11 12 13 14 15 16 17 18 19 20 20	No	1	0.5
	7	No	0.5	0.5
	8	No	0.5	0.5
	9	No	0.5	0
Vaccinates	10	No	0	0.5
(20 horses)	11	No	0	0
	12	No	0	0
	13	No	0	0
	14	No	0	0
	15	No	0	0
	16	No	0	0
	17	No	0	0
	18	No	0	0
	19	No	0	0
	20	No	0	0

Scoring of hi	stopathological lesions:
0 =	No significant lesions.
0.5 =	Rare, small, multifocal glial nodules scattered throughout the parenchyma.
1 =	Mild, nonsuppurative encephalitis characterized by mild multifocal perivascular cuffs with lymphocytes and plasma cells and a rare neutrophil and scattered multifocal glial nodules composed of glial cells with a few mononuclear inflammatory cells. Occasionally within this grade, there may be minimval perivascular cuffing and more moderate scattered glial nodules.
2 =	Moderate nonsuppurative encephalitis characterized by moderate lymphoplasmacytic perivascular cuffs around many vessels and multifocal accumulations of glial nodules scattered throughout the parenchyma.
3 =	Severe nonsuppurative encephalitis characterized by severe and thick lymphoplasmacytic perivascular cuffing with multiple scattered glial nodules throughout the parenchyma.

Viremia:									Ä	ays Pos	t-challen	lge								
Treatment	#	•					6.1	_	4		ŝ		٩		-	8	0	01	14	5
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Vaccinates	10																			
(20 horses)	Π																			
	12																			
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Study Type	Efficacy					
Pertaining to	West Nile Virus					
Study Purpose	Demonstration of efficacy against WNV					
Product Administration	Two doses, administered intramuscularly 21 days apart					
Study Animals	28 horses (19 vaccinates, 9 placebo controls) 4-5 months of age					
Challenge Description	West Nile Virus was administered intrathecally at 14 days (to 10					
	vaccinated and 5 placebo control animals) and 28 days (to 9					
	vaccinated and 4 placebo control animals) after the second					
	vaccination					
Interval observed after	Horses were bled on the day of challenge, twice daily for 6 days					
challenge	post-challenge, once daily for an additional 4 days post-challenge,					
	and on day 14 post-challenge					
Results	The primary outcome was viremia (detection of WNV in the					
	blood). While the test method was quantitative, an animal was					
	considered to be positive (affected by challenge) if any virus was					
	detected in the blood on one or more occasions post-challenge.					
	The number of animals positive for (affected by) viremia at least					
	once is summarized as follows:					
	Controls Vaccinates					
	8/9 (89%) 1/19 (5%)					
	See raw data on the following page.					
USDA Approval Date	August 25, 2008					

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	ad (euthanized on Day 11 due to West Nile Virus)		
ad (euthanized on Day 11 due to West Nile Virus)			

Study Type	Efficac	су			
Pertaining to	West N	Vile Virus (V	WNV)		
Study Purpose	Demor	nstration of s	six month durati	on of immuni	ty against WNV
Product Administration	Two d	oses, admini	istered intramus	cularly 21 day	rs apart
Study Animals	30 hor	ses (20 vacc	inates, 10 placel	bo controls) 4-	-5 months of age
Challenge Description	Challe	nge by West	t Nile Virus was	administered	at 180 days
	(Challe	enge Group	1: 10 vaccinated	l and 5 placeb	o control animals)
	or 243	days (Chall	enge Group 2:	10 vaccinated	and 5 placebo
	contro	l animals) af	fter second vacc	ination	
Interval observed after	Horses	s were bled o	on the day of cha	allenge, twice	daily for 6 days
challenge	post-cl	nallenge, on	ce daily for an a	dditional 4 da	ys post-challenge,
	and on	day 14 post	t-challenge		
Results	The pr	imary outco	me was viremia	(detection of	WNV in the
	blood)	. While the	test method was	s quantitative,	an animal was
	consid	ered to be p	ositive (affected	by challenge)	if any virus was
	detecte	ed in the blo	od on one or mo	ore occasions p	post-challenge.
	The nu	umber of ani	mals positive fo	r viremia at le	east once
	(affect	ed) is summ	arized as follow	vs:	1
		Challenge	Controls	Vaccinates	
		Group	F/F (1000()	2/10/200/	
		1	5/5 (100%)	2/10 (20%)	
		<u>2</u>	$\frac{5}{5}(100\%)$	4/10 (40%)	
		Comoned	10/10(100%)	0/20(30%)]
	Soo ros	w data on th	o following page	2	
	Secial	w uata off th	e tonowing page	U.	
USDA Approval Date	Octobe	er 21, 2009			

Viremia:				Days	Post-c	hallen	ge											
E	Horse		1	C1	0	3		4		S		9	t	9	•			inal
1 reatment	Œ	U AN	I PM	AM	PM	AM	PM	AM	PM	AM	PM	AM PN	, I	<u>م</u>	y 1	0 14	õ +	tcome
	S2			170	170	165	55	105	45								P(sitive
Controls	2			425	20	30	40	85	60	65						z	P.	sitive
(5 horses)	S10			10	300	125	125	80	45								P(sitive
Challenge 1	S11				50	30	40	40	25								P(sitive
	S13				410	110	135	110	55	15						Z	P(sitive
	S1												_			_	Ž	gative
	S3																Ž	gative
	S5																Ž	gative
Version	S6																Ž	gative
	S7			470		45	5										P.	sitive
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	S50		5	535	500	80	100	50	10				_			_	P(sitive
Controls	S53		20	320	380	100	135	45	10								P	sitive
(5 horses)	S54							5		5	5	5				Z	P(sitive
Challenge 2	S55	10	5	95	70	30	25	40									P(sitive
	S59			90	265	20	70	45	45	5							P(sitive
	S46																Ň	gative
	S47							5									P(sitive
	S48																Ž	gative
Vaccinatos	S49			15													P	sitive
(10 horeoe)	S51																Ň	gative
Challenge 2	S52																Ž	gative
	S56																Ž	gative
	S57			S	5												Ğ	sitive
	S58		S														P	sitive
	S60																Ž	gative
Actual value in Blank = Negati N = Not record	plaque-form ve for virus is ed	ing unit solation	s per mil (<5 PFI	lliliter e U eq/mL	quivale .)	nts (PF	U eq/n	ıL) = P	ositive	for vir	us isol	ation						
Positive = affec Negative = viru	cted by challe is was detecte	nge if v ed in the	irus was blood c	: detecte m zero (d in the occasio	e blood ns post-	on one challer	or moi nge.	re occa	sions p	ost-chi	allenge.						

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	-PM-1009						
	North Dako	ota Site:						
	Group	Vaccin	nated	Cont Preg	firmed nant	Foals		Parturition Rate
	1 st trimester product	/ 143		127		114	1	90%
	1st trimester	r/ 59		54		49		91%
	2 nd trimester	r/ 6		6		6		100%
	3 rd trimester	./ 140		117		117		100%
	Total –	348		304		286		94%
	Total –	289		250		237		95%
	Total –	1y 59		54		49		91%
	placebo on	ly						
	Study 2013 Misssouri S	-PM-1009 /ite:						
	Group	Vaccina	ated	Confi Pregr	rmed ant	Foals	Pa R	arturition ate
	2011 3 rd	5		5		5	10	00%
	2012 1 st	1		1		1	10	00%
	2012 2 nd	53		43		39	91	%
	2012 3 rd	26		26		25	96	5%
	Total –	85		75		70	93	%
	Study 2014 North Dako	-PM-1009 ta Site:	1					
	Group	Vaccinated	Conf Pregi	irmed nant	Foaled	l Parturi Rate	ition	Foals Survived to End of Observation Period
	2 nd trimester	52	52		52	100%		51*
	3 rd trimester vaccinated	69	69		67**	97.1%		67
	*Lost foal aff **One mare cooperator.	firmed by study died due to cau	y coope ises oth	erator to er than	be due vaccina	to causes o tion, as affi	ther t rmed	han vaccination. by study
LISDA Annuaral	All other foal	$\frac{15 \text{ were normal}}{12 2014}$	and he	aitny				
USDA Approval	Date September	12, 2014						

Study Type	Safety						
Pertaining to	All fractions						
Study Purpose	To demonstra	ate safety u	nder field cond	itions			
Product	Two doses, a	dministered	l intramuscular	:ly 3 − 4 w	eeks apar	t	
Administration							
Study Animals	556 horses, in	ncluding 43	8 foals betwee	n 2 month	is and app	roximately	y 1 year
	of age						
Challenge	Not applicab	le					
Description							
Interval	Not applicab	le					
observed after							
challenge							
Results	Horses were resolution of second vacci	observed at any observent nation.	least daily folled reactions. O	lowing ea bservation	ch vaccina ns ended 1	ation, until l4 days aft	er the
	There were n from causes	o systemic affirmed by	reactions obser licensee not as	rved at any ssociated	y of the si with vacci	tes. One h nation.	orse died
	Scoring Metl 0 = No reacti 1 = Localized detectable on 2 = Localized 3 = Localized circumscribe	nod for Inje on d swelling a ly by palpa d visible sw d visible sw d and painf	ction Site Reac t or near the in tion. Not painf elling at or nea elling at or nea ul when palpat	ctions: jection situl. ar the inject ar the injected.	e which is ction site. ction site.	s not visib Not painfu Raised,	le; 11.
	Local injection	on site react Total Number Of Vaccinet	ions are summ Number Of Vaccinates Administere	arized bel Vaccina Tran Injecti Swe	ow across tes With sient on Site lling	the sites: Numb Nor Vacci	per Of mal inates
		es	d 2 doses	After	After	After	After
				1 st dose	2 nd dose	1 st dose	2 nd dose
	Missouri	315	314	(1.0%)	(2.9%)	(99.0%)	505 (97.1%)
	Oklahoma	110	110	1 (0.9%)	2 (1.8%)	109 (99.1%)	108 (98.2%)
	Texas	131	131	0 (0%)	0 (0%)	131 (100%)	131 (100%)
	Total	556	555	4 (0.7%)	11 (2.0%)	552 (99.3%)	544 (98.0%)
	Results from	each site ar	e summarized	on the fol	lowing pa	ige.	

Summary	Number Of	Number Of Vaccinates Administered 2 doses	Vaccinates With Transient Injection Site Swelling		Number Of Normal Vaccinates		
Age	vaccinates		After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose	
2-4 months	55	55	0	0	55	55	
5-7 months	8	8	0	0	8	8	
8-11 months	1	1	0	0	1	1	
1 year	170	170	1	2	169	168	
\geq 2 years	81	80	2	7	79	73	
Total	315	314	3	9	312	305	

Horse No.	Age	Reaction Description	Injection #	Day	Score	Resolution Day
10	11 y	Swelling on day 3, 5.5 cm x 2.25 cm x 5mm	2	3	2	7
22	8 y	Swelling on day 3, 12 cm circle, raised 1.5 cm, painful,	2	3	3	7
129	1 y	Swelling on day 3, 2.3 cm circle, raised 4 mm, painful but no heat	2	3	3	7
183	1 y	Swelling on day 7, raised lesion 1.5 cm circle, height 0.2 cm	1	7	2	14
183	1 y	Swelling on day 1, 3 cm lesion, not raised but palpalble	2	1	1	3
222	9 y	Swelling on day 3, 6 cm x 7 cm x 1.2 cm, raised lesion hard and painful	2	3	3	7
266	10 y	Swelling localized in several places unsure if related to vaccine	1	1	2	3
266	10 y	Swelling small palpapable mass ~ 2 cm size, still present day 3 no worse	2	1	2	3
271	13 y	Swelling 5cm circle, raised 5 mm, solid and painful	2	3	3	7
288	8 y	Swelling < 2 cm, raised lesion ~ 1 mm deep	1	3	2	7
288	8 y	Swelling ~ 8.5 cm circle raised ~ 1.3 cm, painful, not hot to touch	2	3	3	7
300	10 y	Swelling 6 cm circle, solid swelling not painful	2	3	2	7

Oklahoma Site:

Summary	Number Of	Number Of Number Of VaccinatesVaccinates Vaccinates		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		
4-6 months	49	49	1	1	48	48		
1 year	25	25	0	1	25	24		
\geq 2 years	36	36	0	0	36	36		
Total	110	110	1	2	109	108		

Horse No. Age Reaction Description Injection # Day Score Resolution Day Swelling redness painful injection area 6 cm in diameter, reaction subsided in 19-A 4 m 10 days 7 3 17 1 2 33-A 5 m Small swelling, 3 cm diameter, subsided in 3 days 2 1 4 Mid-sized swelling, 5 cm diameter, reduced to 2.5 cm in 6 days; small, hard 2 $\,$ 43 1 y Study End 2 2 cm at 10 days, probable subcutaneous leakage 1

Summary	Number Of Vaccinates	Number Of Vaccinates Administered	Vaccinates With Transient Injection Site Swelling		Number (Vacci	Of Normal inates
Age		2 doses	After 1 st dose	After 2 nd dose	After 1 st dose	After 2 nd dose
7-9 months	130	130	0	0	130	130
\geq 2 years	1	1	0	0	1	1
Total	131	131	0	0	131	131