

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	48W5.R1
True Name	Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Killed Flavivirus Chimera, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Encevac-T + WNV with Havlogen - Merck Animal Health
Date of Compilation Summary	December 19, 2017

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.

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Study Type	Efficacy
Pertaining to	Clostridum tetani
Study Purpose	Demonstrate efficacy against C. tetani
Product Administration	One dose administered subcutaneously.
Study Animals	Ten guinea pigs (5 females and 5 males, 450-550g)
Challenge Description	Not applicable
Interval observed after	Six weeks after vaccination, guinea pigs were bled for serological
challenge	testing.
Results	Efficacy of <i>C. tetani</i> was demonstrated in laboratory animals according to 9CFR 113.114(c). Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool. Pooled Guinea Pig Antitoxin titer (A.U./mL) 2.082
USDA Approval Date	June 15, 2010

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Study Type	Efficacy			
Pertaining to	Eastern Equine E	Encephalomyelitis (EEE)	
Study Purpose	Demonstrate effi	cacy against EEE		
Product Administration	Two doses admir	nistered intramuscu	larly 3 weeks ap	oart.
Study Animals	Twelve guinea pi	igs, 10 vaccinates a	nd 2 controls, ea	ach 300-500g
Challenge Description	Not applicable			
Interval observed after	14 days post 2nd	vaccination, guine	a pigs were bled	for
challenge	serological testin	g.		
Results	according to 9CF Satisfactory test	was demonstrated in FR 113.207(b). The result is a Virus New 20 vaccinates (2 nd states).	utralization Tite	r of ≥ 1:40 in
	Treatment		Test	
	group	Results	Disposition	
	Vaccinates	$17/20 \ge 1:40$	Satisfactory	
	Controls	2/2 <1:4	Ballstactory	
USDA Approval Date	June 15, 2010		·	

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Study Type	Efficacy			
Pertaining to	Western Equine	Encephalomyelitis	(WEE)	
Study Purpose	Demonstrate effi	cacy against WEE		
Product Administration	Two doses admir	nistered intramuscu	ılarly 3 weeks ap	art.
Study Animals	Twelve guinea p	igs, 10 vaccinates a	and 2 controls, ea	ach 300-500g
Challenge Description	Not applicable			
Interval observed after	14 days post 2nd	vaccination, guine	a pigs were bled	
challenge	for serological te	sting.		
Results	according to 9CF	result is a Virus Ne	Ž	
	Treatment		Test	
	group	Results	Disposition	
	Vaccinates	9/10 ≥ 1:40	Satisfactory	
	Controls	2/2 <1:4	Butisfactory	
USDA Approval Date	June 15, 2010			

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Study Type	Efficacy			
Pertaining to	West Nile Viru	ıs		
Study Purpose			gainst West Nile	Virus
Product Administration			ntramuscularly 3	
Study Animals				used at 6 months of
	age			
Challenge Description	20 horses (10 v	vaccinates a	and 10 control) w	ere challenged with
				on. The remaining
	20 horses were	e challenged	d 91 days post-2 ⁿ	d vaccination.
Interval observed after				Illenge for clinical
challenge			re taken at days 0	
	_		_	gy was performed on
D. K	samples taken			
Results				nonstration of clinical
	_	-	ase observed in h	_
			field conditions	(i.e. mentation,
	Group	# of	Presence of	
	Group	Animals	clinical signs	
	Vaccinates	20	7	
	Controls	20	13	
	Controls		13	
	Viremia was d	efined as th	e presence of a v	virus titer ≥ 5 PFU/mL
	of serum on an		•	_
		# of		
	Group	Animals	Viremia	
	Vaccinates	20	14	
	Controls	20	20	
				ulla or cervical cord
			l lesions of at lea	
		minimal ch	anges in these tis	sues were classified as
	unaffected.		I	_
		# of		
	Group	Animals	Encephalitis	_
	Vaccinates	20	9	_
	Controls	20	19	
	Daw d-t1	o44_ 1		
LICDA A	Raw data show		ieu pages.	
USDA Approval Date	March 27, 200	9		

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Overview of Challenge Groups

	hallenge Grouj	Challenge	Challenge Day
Group	Horse No.	Group	Post 2 nd -Vacc
Vaccinate	206	1	61
Vaccinate	214	2	91
Vaccinate	301	1	61
Vaccinate	316	1	61
Vaccinate	318	1	61
Vaccinate	324	1	61
Vaccinate	326	2	91
Vaccinate	331	1	61
Vaccinate	332	2	91
Vaccinate	333	2	91
Vaccinate	334	2	91
Vaccinate	335	2	91
Vaccinate	609	2	91
Vaccinate	614	1	61
Vaccinate	615	1	61
Vaccinate	618	1	61
Vaccinate	620	2	91
Vaccinate	622	1	61
Vaccinate	623	2	91
Vaccinate	624	2	91
Control	205	2	91
Control	222	2	91
Control	300	1	61
Control	302	1	61
Control	307	1	61
Control	308	1	61
Control	310	1	61
Control	311	2	91
Control	313	1	61
Control	313	2	91
Control	321	2	91
	323	1	61
Control		2	91
Control	325	1	
Control	396		61
Control	611	2	91
Control	613	1 2	61
Control	616	2	91
Control	617	1 2	61
Control	625	2	91
Control	626	2	91

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Clinical scores of vaccinate horses with mentation on days post challenge with WNV. Table 1.

[rante 1.		11111	Clinical scores	COLE	20 2	- 1	vaccinace	- 1	HOLSES	TA S	With mentation	HCGI	101	on days post	178	- 1	CEIG	cuarrenge	- 1	WALLE MINV.	. AND	
Treatment	Horse								ၓ	Scores	S d	nys po	st-ch	lleng	on days post-challenge with WNV	ş							
Group	No.	7	0	-	2	8	4	2	9	7	80	6	9	=	12	13	14	15 1	16 1	17 1	18	19 2	20 21
Vaccinate	206	0	0	0	0	0	0	0	0	0	0	2	0	-	0	0	0	0	0	0		0	0
Vaccinate	214	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	Н	0	0
Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Н	0	0
Vaccinate	316	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0		0	0
Vaccinate	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	324	0	0	0	0	0	0	0	0	0	0	-	0	0	8								
Vaccinate	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	331	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	-	0	0
Vaccinate	333	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0			0
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
Vaccinate	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	609	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0		0	0
Vaccinate	614	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	615	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0			0
Vaccinate	618	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0		-	0
Vaccinate	620	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0
Vaccinate	622	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	0		0	0
Vaccinate	623	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0 0
Vaccinate	624	0	0	0	0	0	0	0	-	0	8	0	0	0	0	0	0		0	0		0	0 0

(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe (.) Euthanized for humane reasons

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Clinical scores of control horses with mentation on days post challenge with WNV. Table la.

	2	٥	٥	٥		۰	٥	٥		٥		۰	٥	٥	۰	٥			٠	۰	
	20	0	0	0	-	٥	٥	٥	-	۰	٠	٥	۰	۰	۰	0	٠	٠	٠	0	
	19	0	0	0		0	0	0	-	0		0	0	0	0	0				0	
	18	۰	۰	۰		0	۰	۰		0		0	0	۰	0	۰				0	
	17	0	0	0	-	0	0	0		0		0	0	0	0	0				0	
	91	0	0	0	,	0	0	0		0		0	0	0	0	0				0	
	15	0	0	0		0	0	۰	,	0		0	0	0	0	0				0	
	4	٥	0	0		0	٥	٥		0		0	0	0	0	0				0	-
Š	5	0	0	0		0	0	0		0	2	0	0	0	0	0				0	
e with	2	٥	0	0		0	0	٥	0	0	0	0	0	0	0	0				0	-
guelle	F	0	0	0		0	•	0	2	0	0	0	0	0	0	0				0	-
st-chs	5	0	0	0	8	-	0	0	01	01	0	0	0	0	0	2		N	ю	N	
ys po	6	0	0	2	0	0	0	0	0	0	2	0	0	-	0	0	2	2	0	0	6
on da	60	٥	0	0	0	0	0	0	0	0	-	0	0	0	0	2	2	0	0	0	N
Scores* on days post-challenge with WNV	_	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ro.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	o	0	0	0	0	0	0	0	0	o	0	0	0	0	0	0	0
	m	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	~	۰		0	0	0	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	_	16	N		O.				_	,00	_	es.	m	10	10	_	m	10		10	40
Hores	Š.	302	222	300	305	307	308	310	311	313	321	322	323	325	396	611	613	616	617	529	928
toot	4	lon	lor	ioi	loi	loi	loi	Ioi	ioi	lou	lou	lou	loi	ioi	rol	ioi	not	lou	Irol	100	10
Treatment	Group	Control	Confrol	Control	Control	Control	Control	Control	Control												
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(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe(.) Buthanized for humane reasons

165A 48W5.R1 Page 8 of 18 Clinical scores of vaccinate horses with paresis on days post-challenge with WNV. Table 2.

Mov. Horse Horse	_	_	_	_		_	_	_	_										_	_	_	_	
Horse -1 Scores* on days post-challenge with WNN 10 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 206 0		21	0	0	0	0	0		0	0	0	0		0	۰	0	0	0	0	0	۰	0	
Horse -1 Scorres* on days post-challenge with WINA No. -1 0 1 2 3 4 5 6 7 8 10 11 12 13 14 15 16 17 18 206 0		20	0	۰	0	۰	0		٥	0	٥	0		0	0	0	0	0	0	0	0	٥	l
Horse -1 0 1 2 3 4 5 6 7 8 9 10 11 12 14 15 16 17 206 0		19	0	0	0	۰	۰		0	0	0	0		0	0	0	0	0	0	0	0	٥	1
Horse -1 0 1 2 3 4 5 6 7 8 10 11 12 13 14 15 16 206 -1 0 1 2 3 4 5 6 7 8 9 10 12 13 14 15 16 206 0 <th></th> <th>18</th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th></th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th>,</th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th>0</th> <th>o</th> <th>۰</th> <th>۰</th> <th>1</th>		18	0	0	0	0	0		0	0	0	0	,	0	0	0	0	0	0	o	۰	۰	1
Horse No. -1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 206 0		17	٥	0	o	o	o		۰	٥	o	0		0	0	0	o	0	0	o	0	٥	1
Mov. 1 Scores* on days post-challenge with MINA MINA MINA MINA. Hor. 1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 206 0		16	٥	0	o	o	0		٥	0	0	0		0	0	0	0	0	0	0	0	0	1
Horse		15	۰	o	0	o	0		٥	0	0	0		0	0	0	0	0	0	٥	٥	٥	1
Horse -1 0 1 2 3 4 5 6 7 206 0<		14	۰	0	0	0	0		٥	0	0	0	6	٥	0	0	0	0	۰	۰	۰	۰	1
Horse -1 0 1 2 3 4 5 6 7 206 0<	WM	13	۰	0	0	0	٥		٥	0	0	0	-	0	0	0	0	0	٥	0	0	۰	l
Horse -1 0 1 2 3 4 5 6 7 206 0<	e with	12	0	0	0	0	٥	2	٥	0	0	0	0	0	0	0	0	0	٥	0	0	۰	١
Horse -1 0 1 2 3 4 5 6 7 206 0<	alleng	=	0	0	0	0	0	0	٥	o	0	0	0	0	0	0	0	0	0	٥	o		l
Horse -1 0 1 2 3 4 5 6 7 206 0<	ost-ch	9	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	l.
Horse -1 0 1 2 3 4 5 6 7 206 0<	ays po	6	61	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	۰	
Horse -1 0 1 2 3 4 5 6 206 0<	ou d	8	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	o	N	ľ
Horse -1 0 1 2 3 4 5 6 206 0<	cores	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	A Westernamen
Horse No. -1 0 1 2 3 4 206 0	Š	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Horse No. -1 0 1 2 3 206 -1 0 1 2 3 208 0 0 0 0 0 0 0 301 0		ď	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Horse -1 0 1 2 206 0 0 0 0 0 206 0 0 0 0 0 0 214 0 <t< th=""><th></th><th>4</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>۰</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th>0</th><th></th></t<>		4	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	
Horse No. -1 0 1 206 -1 0 1 208 0 0 0 0 214 0 0 0 0 318 0 0 0 0 324 0 0 0 0 332 0 0 0 0 334 0 0 0 0 609 0 0 0 0 614 0 0 0 0 618 0 0 0 0 618 0 0 0 0 620 0 0 0 0		3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Horse No1 0 206 0 0 214 0 0 316 0 0 318 0 0 324 0 0 328 0 0 338 0 0 338 0 0 614 0 0 615 0 0 618 0 0		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Horse No1 No1 No1 No1 206 0 214 0 316 0 316 0 324 0 324 0 324 0 609 0 614 0 615 0 620 0 62		٦	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Horse No. No. 206 214 316 318 324 324 338 338 338 609 614 618		0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	٥	
		7	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	Horse	No.	206	214	301	316	318	324	326	331	332	333	334	335	609	614	615	618	620	622	623	624	
Treatmed Group Vaccina	Treatment	Group	Vaccinate																				

(a) Observation were scored as D= Normal, 1=Mild, 2=Moderate, 3=Severe
 (.) Buthanized for humane reasons

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Clinical scores of control horses with paresis on days post-challenge with WNV.

Scores' on days post-challence with WNV Table 2a.

9 10 11 12 13 14 15 16 17 18 19 20 21 0 <	Horse	Scores	Scores, o	Scores	Sel	= .	on days	Na po	post-challenge with WNV	obuo.	WILL	2		-	-	-	-							
	No1 0 1 2 3 4 5	0 1 2 3 4	1 2 3 4	2 3 4	9 4	4		50		9	_	80	6	-	-	-	-	-	-	-		19	20	2
	205 0 0 0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0	0 0	0	0	Н		Н	Н		0	0		Н				٥	0	0	0	0
	222 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0			- 1	Н		0	0	0	_					0	0	0	0	0
	300 0 0 0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0	0						0	0	0	0					0	0	0	0	0
	302 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0	-	0		_		0	0	8										
	307 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0		0		_		0	0	0						0	0	٥	۰	0
	308 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0	_	0	_	_		0	0	0	0					0	0	٥	٥	0
	310 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0		0	_	_		0	0	0	0					0	0	0	0	0
	311 0 0 0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0	0		0		_		0	0	0		Н	Н	Н			-			
	313 0 0 0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0	0		0		_		0	0	8			_			0	0	0	0	0
	321 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0						0	0	0	0				Н					
	322 0 0 0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0	0		0	_	_		0	0	0	0					0	0	0	0	0
	323 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0		0	_	_		0	0	0						0	0	0	0	0
	325 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0			0	-		0	0	0						0	0	0	0	0
	396 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0	0 0	0			0			0	0	0	0					0	0	0	0	0
	611 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0			0	_		ev.	0	0						0	0	0	0	0
	613 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0			0	_		0	-								٠	٠		
	616 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0	0	0			0	_		0	0	0			_			,	٠	٠		
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	617 0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0	0		0	_	-		0	0	2		Н	Н	Н	Н			٠	٠	٠
	0 0 0 0 0 0 0	0 0 0 0	0 0 0	0 0 0	0	0		0				0	0	2						0	0	0	0	0
	0 0 0 0 0 0 0 959	0 0 0 0	0 0 0	0 0	0	0		0		_		0	60	-			_							

(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe(.) Euthanized for humane reasons

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Table 3.Clinical scores of vaccinate horses with fasciculation on days post-challenge with WNV.

Treatment	Horse								S	Scores* on days post-challenge with WNV	ou d	ays po	st-cha	llenge	with	Š								
	No.	÷	0	-	2	3	4	2	9	7	8	6	10	=	12	13	14	15	16	17	18	19	20	2
	206	0	0	0	0	0	0	0	0	0	0	2	0	-	-	0	0	0	0	0	٥	0	0	٥
	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	316	0	0	0	0	0	0	0	0	0	0	0	0	~	-	0	0	0	0	0	0	0	0	0
Vaccinate	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	324	0	0	0	0	0	0	0	٥	0	0	-	0	0	~								,	
Vaccinate	326	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	331	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	333	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-		,			,	,	
Vaccinate	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	609	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	614	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	615	0	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	618	0	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	620	0	0	0	0	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	622	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	623	0	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	624	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	۰
Ohopwatt	don way	Ι.	anovad a	0 0 0	Moveme	Law.	-W-	7	=Modovs	visto.	2=0	Correction	١.								l	1	l	

Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe Euthanized for humane reasons @ C

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Table 3a. Clinical scores of control horses with fasciculation on days post-challenge with WNV.

Treatment	Horse								Š	Scores_	on d	on days post-challenge with WNV	st-cha	lleng	with	2								
Group	No.	7	0	-	7	8	4	2	9	7	80	8	10	11	12	13	14	15	16	17	18	19	20	21
Control	308	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	222	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	300	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0
Control	302	0	0	0	0	0	0	0	0	0	0	-	N											
Control	307	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	308	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	310	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	311	0	0	0	0	0	0	0	0	0	0	0	0	9	0									
Control	313	0	0	0	0	0	0	0	0	0	0	N	N	CN.	-	0	0	0	0		0	0	0	0
Control	321	0	0	0	0	0	0	0	0	0	0	0	0	0	N	Q.								
Control	322	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	323	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	٥	0
Control	396	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	611	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	613	0	0	0	0	0	0	0	0	0	0	Q.												
Control	616	0	0	0	٥	٥	0	0	0	0	0	0	es											
Control	617	0	0	0	٥	0	0	0	0	0	0	0	es											
Control	625	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Control	626	0	0	0	0	0	0	0	0	0	2	0		-							,			
al Observation	tion were		scored ,	as 0=		Normal,	1=Mil	1d, 2:	-Made	2=Moderate,		3=Severe												

Observation were scored as 0= Normal, 1=Mild, 2-Moderate, 3=Severe Euthanized for humane reasons

165A 48W5.R1 Page 12 of 18 Clinical scores of vaccinate horses with ataxia on days post-challenge with WWV. Table 4.

		- August	ı	1000				١			ŀ									Buch			ł	l	ı
Ę	Treatment	Horse								ഗ്	corres	p uo	ays po	Scores" on days post-challenge with WNV	alleng	e with	Š		1						
9	Group	No.	7	0	-	7	e	4	ю	9	7	60	o	10	:	12	13	14	15	16	17	18	19	20	72
s'	Vaccinate	206	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N	Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Va	Vaccinate	316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	٥	0	0	0	0	0
8	Vaccinate	324	0	0	0	0	0	0	0	0	0	0	0	0	0	е				-					
× ×	Vaccinate	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N/a	Vaccinate	331	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	٥	0
8	Vaccinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	۰
Α,	Vaccinate	333	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	۰
>	Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	o	0	0	0	e		-					
×	Vaccinate	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	609	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	614	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0
×	Vaccinate	615	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	۰
>	Vaccinate	618	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	620	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>	Vaccinate	622	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	Vaccinate	623	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
\$	Vaccinate	624	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0
(4)	(a) Observat	are tempo	ı.	anovad a	20 De	LemvoN .	9	- N-1	2	=Modeva	Yafa	3-6	Coursers				l	ĺ	l	l	١	l	l	l	l

(a) Observation were scored as 0" Normal, 1=Mild, 2=Moderate, 3=Severe (.) Euthanized for humane reasons

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		_	_	_											
		20	0	٥	0		0	0	0		0		0	0	0
Wav.		19	0	0	0		0	0	0		0		0	0	0
h Wil		18	۰	۰	0	,	0	0	0		0		0	0	0
with		17	0	۰	0		0	0	0		0		0	0	0
enge		16	0	0	0		0	0	0		0		0	0	0
ball		15	0	0	0		0	0	0		0		0	0	0
post-challenge	ļ	14	0	0	0		0	0	0		0		0	0	0
ng s	on days post-challenge with WNV	13	0	0	0		0	0	0		0	3	0	0	0
ataxia on days	ge wit	12	0	0	0	,	0	0	0	0	0	٦	0	0	0
ia or	allen	Ξ	0	0	0		0	0	0	1	1	0	0	0	0
taxi	ost-ch	10	0	0	0	3	0	0	0	0	1	0	0	0	٥
th	ays p	6	0	0	0	0	0	0	0	0	0	0	0	0	0
s w	ouo	8	0	0	0	0	0	0	0	0	0	0	0	0	0
horses with	Scores"	7	0	0	0	0	0	0	0	0	0	0	0	0	0
10.	S	9	0	0	0	0	0	0	0	0	0	0	0	0	0
control		2	0	0	0	0	0	0	0	0	0	0	0	0	0
of		4	0	0	0	0	0	0	0	0	0	0	0	0	0
res		3	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinical sco		8	0	0	0	0	0	0	0	0	0	0	0	0	0
ica]		-	0	0	0	0	0	0	0	0	0	0	0	0	0
CLL		0	0	0	0	0	0	0	0	0	0	0	0	0	0
đa.		7	0	0	0	0	0	0	0	0	0	0	0	0	0
Table 4a.	Horse	No.	205	222	300	302	307	308	310	311	313	321	322	323	325
	Treatment	Group	Control												

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386 613 614 615 616 617

Control Control

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Control

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(a) Observation were scored as 0= Normal, 1=Mild, 2=Noderate, 3=Severe

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Table 5. Summary of Clinical Observations for Primary Outcome/Case Definition

		Horses that had one or more days with mild, moderate or severe scores in any of the categories or that required euthanasia									
Horse No.	Vaccine Group	Mentation	Paresis	Fasciculations	Ataxia	Euthanasia					
206		+	+	+	+						
214		+									
301											
316		+		+							
318											
324		+	+	+	+	+					
326											
331											
332	<										
333	Vaccinate	+		+							
334	ina	+	+	+	+	+					
335	9										
609											
614											
615											
618											
620											
622	1										
623											
624		+	+		+						
205											
222											
300		+		+							
302		+	+	+	+	+					
307		+		The second secon							
308											
310											
311		+	+	+	+	+					
313		+	+	+	+						
321	Co	+	+	+	+	+					
322	Control										
323	₩.										
325		+									
396			1								
611		+	+	+							
613		+	+	+		+					
616		+	1	+		+					
617		+	+	+	+	*					
625		+	+	+							
626		+	+	+	-	+					

⁽⁺⁾ Clinical signs

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Table 1. Viremia in vaccinate and control horses on days post-challenge with WNV.

Treatment	Horse			(pfu/m			retum o				challer	nge wit	h WNV	
Group	No.	0	1	2	3	4	5	6	7	8	9	10	14	21
Vaccinate	206	<5	20	210	65	<5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5
Vaccinate	214	< 5	< 5	30	10	-	< 5	< 5	< 5	<5	< 5	<5		<5
		_	_			< 5							< 5	_
Vaccinate	301	< 5	< 5	15	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	316	< 5	5	35	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	318	< 5	< 5	175	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	324	< 5	10	130	25	5	< 5	< 5	< 5	< 5	< 5	< 5		
Vaccinate	326	< 5	40	520	70	40	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	331	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	332	< 5	5	55	25	45	15	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	333	< 5	5	70	175	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	334	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	-
Vaccinate	335	< 5	< 5	15	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	609	< 5	< 5	15	45	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	614	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	615	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5
Vaccinate	618	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	620	< 5	< 5	20	20	45	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	622	< 5	< 5	10	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	623	< 5	< 5	95	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	624	< 5	< 5	< 5	<5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5	< 5
Control	205	< 5	5	80	155	30	< 5	< 5	< 5	< 5	< 5	< 5	<5	<5
Control	222	< 5	< 5	165	45	75	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	300	< 5	55	265	45	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	302	< 5	< 5	5	5	10	15	< 5	< 5	< 5	< 5	< 5		-
Control	307	< 5	< 5	15	15	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5
Control	308	< 5	< 5	20	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	310	< 5	< 5	45	35	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	311	< 5	<5	10	10	10	< 5	< 5	< 5	< 5	<5	<5	-	-
Control	313	< 5	30	225	370	15	< 5	< 5	< 5	< 5	< 5	<5	< 5	<5
Control	321	< 5	<5	20	15	35	5	< 5	< 5	< 5	< 5	< 5		
Control	322	< 5	20	15	45	20	< 5	< 5	<5	< 5	<5	< 5	< 5	< 5
Control	323	< 5	60	460	75	5	< 5	<5	<5	< 5	<5	<5	< 5	<5
Control	325	< 5	25	235	70	30	<5	<5	<5	< 5	<5	<5	< 5	< 5
			_	_									_	< 5
Control	396	< 5	5	55	20	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	
Control	611	< 5	< 5	50	30	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	613	< 5	< 5	95	35	5	< 5	< 5	< 5	< 5	< 5			
Control	616	< 5	< 5	35	40	40	< 5	< 5	< 5	< 5	< 5	< 5		
Control	617	< 5	5	45	40	40	10	< 5	< 5	< 5	< 5	< 5		
Control	625	< 5	5	320	140	65	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	626	< 5	15	470	225	175	< 5	< 5	< 5	< 5	< 5	-	-	-

(.) Euthanized for humane reasons

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Table 1. Histopathology of neural tissues post-challenge with virulent WNV

	Vaccine	with virulent W Histopatho	ology of neural tis	sue
Horse No.	Group	Post-ch	allenge with WNV	/*
	алоор	Cervical Cord	Medulla	Pons
206		0	0	0
214		1	0	1
301		0	0	0
316	1	0	1	0
318		0	0	0
324		1	1	1
326		2	2	2
331		0	0	0
332	<	0	0	0
333	Vaccinate	1	0	1
334	ā	2	2	2
335	6	0	0	0
609		0	0	1
614		0	0	0
615		0	0	0
618		0	0	0
620		0	0	0
622		0	0	0
623		0	1	0
624		0	1	1
205		1	1	0
222		1	1	1
300	J	1	1	0
302		3	3	3
307		1	1	0
308		0	0	0
310		1	1	1
311		2	2	2
313	_	0	1	1
321	Contr	1	1	2
322	ntrc	1	0	0
323	<u>o</u>	0	1	0
325		1	1	ō
396		0	1	1
611		1	1	1
613		3	3	3
616		1	2	2
617		1	2	3
625		i i	1	0
626		2	3	3

*Histopathology scores: 0 = no apparent lesions in section or minimal changes apparent; 1 = mild changes present; 2 = moderate changes present; 3 = severe changes present or very severe lesions with extensive distribution

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Study Type	Safety						
Pertaining to	ALL						
Study Purpose	To demonstrate safety under fiel	d condition	S				
Product Administration	Two doses administered intramu						
Study Animals	1,255 horses from 5 states. 570	horses were	e 6 months of age or				
	younger at time of the intial vacc						
Challenge Description	Not applicable						
Interval observed after	Horses were observed immediate	•	ng vaccination and then				
challenge	daily for 21 days post-vaccination	n					
Results			1				
	Adverse Events	Number					
	Injection Site Swelling*	102					
	<1.5cm	24					
	1.5-5.0cm	57					
	>5.0cm	21					
	Injection site pain	17					
	Lethargy/Depression	6					
	Diarrhea	3					
	Soft Feces 1						
	Anorexia	6					
	Not Drinking	1					
	Increased Respiratory Rate	1					
	Nasal Discharge	1					
	Hoof Abscess	1					
	Enlarged Lymph Node	1					
	Hives	1					
	Unilateral Epistaxis	1					
	Colic Episode**	1					
	Horses with no reaction	1,149					
	*Injection site swellings resolved 3-7 d **Horse was euthanized; suspected due affirmed by licensee.						
USDA Approval Date	February 18, 2010						

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