

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	49W5.A0
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza-West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vetera Goldxp + VEE - No distributor specified
Date of Compilation Summary	November 27, 2020

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
Study Type	
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	6 weeks after the injection, 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	February 15, 2011

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	February 15, 2011

Study Type	Efficient
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	February 15, 2011

Study Type	Efficacy
Pertaining to	Western equine encephalomyelitis
Study Purpose	Demonstration of efficacy against Western equine
	encephalomyelitis
Product Administration	Two doses, administered intramuscularly, 14-21 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 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	February 15, 2011

Study Type	Efficacy									
Pertaining to	Equine herp	besvirus	type 1 (E	EHV-1)						
Study Purpose	Demonstrat EHV-1	ion of ef	ficacy ag	gainst respiratory disease caused by						
Product Administration	Two doses,	adminis	tered intr	ramuscularly, 21 days apart						
Study Animals	40 horses (2	20 vaccii	nates, 20	controls), 4-5 months of age						
Challenge Description	Equine herp	pesvirus	type 1 ad	lministered 15 days post-final						
	vaccination									
Interval observed after	Horses were	e observ	ed daily f	for 14 days post-challenge						
challenge										
Results	See raw dat	a on foll	owing pa	ages.						
	signs of res classified a	piratory s "norm lassifica us 1	disease. al", "mil tion of th	or the presence of nasal discharge as The severity of nasal discharge was ld", or "moderate" according to the ne nasal scores.						
	The number of horses in each category were:NormalMildModerateControl01001010Vaccine611									
USDA Approval Date	January 28,	2009								

Nasal Discharge:

								tchall								
Treatment	ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	1					1.5			1.5	1.5	1	1.5				
	2						1.5		1.5	1.5	1	1.5	1.5	1		
	3						1.5			1.5	2			1.5		
	4			1		2	1.5		1.5	1.5	1.5	1.5				1.5
	5				2	2	2	1	4	2	2	1.5	1.5		1.5	
	6			1		4	6	4	4	4	4	2	2	2		
	7					1.5	1.5	1.5	1.5	1.5	2	4	1		1	1
	8								1.5	2	2	4	1.5	4	2	1.5
	9				1	1.5	1.5	1.5	1.5	1.5	2	1.5				
Controls	10			1			1		1.5	1.5	2	4	4		1.5	1.5
(20 horses)	11						1.5	1.5	1.5		2		1.5	1.5	1.5	
	12						1.5	1.5		2						1.5
	13		İ				2	1.5	1.5	2	2	2	1.5	1.5	1.5	4
	14				1.5	2		1.5		1.5	1.5	1.5			2	2
	15				1	2	1.5	1	1.5		4		1		4	1.5
	16					1.5	1.5	2	2	2	2	1.5	1	1	4	2
	17					1.5		1			1.5	2		1.5	1.5	
	18						1	1.5	1.5	4	4	2	1.5	4	1.5	2
	19				1	2	1.5		1.5	2	4	1	1.5		1	
	20						1.5	1.5	2	1.5	2				1.5	
	1					1		1				1.5				
	2				1											
	3						1	1.5	4		1.5	1.5			1	
	4				1						2	1				
	5				1				1	1						
	6				1	1.5						1.5	2	2	2	1.5
	7							2					1.5			
	8															
	9					2	1.5	2	2	6	2	1.5		1.5	4	2
Vaccinates	10								1				1	1.5		
(20 horses)	11				1		1.5		2	2	1	1.5				
,	12				1		1.5	2	1.5	2	2	2		2	2	1.5
	13				1.5						1.5	1.5			1.5	1.5
	14		İ				l	1	1		l	1	l		1.5	
	15		İ		1		l		l		l		l			
	16				1		1.5	1.5	1			1.5				
	17															
	18						1			1.5		1.5				
	19														6	2
	20		l				l		l		l		l			

Day Postchallenge

Scoring:

Blank is 0 =none;

1 = slight serous, as may be observed in both normal and diseased horses;

- 1.5 = very slight mucopurulent discharge;
- 2 = moderate clear serous discharge, or slight mucopurulent discharge;
- 3 = abundant serous discharge;
- 4 = moderate mucopurulent discharge;
- 6 = heavy mucopurulent discharge

Study Type	Efficacy											
Pertaining to	Equine herpesvirus ty	/pe 4 (EHV-4)										
Study Purpose	Demonstration of effi EHV-4		tory disease cau	ised by								
Product Administration	Two doses, administe	ered intramuscularly	, 21 days apart									
Study Animals	40 horses (20 vaccina	ates, 20 controls), 4 i	nonths of age									
Challenge Description	Equine herpresvirus t vaccination	ype 4 administered	14 days post-fin	al								
Interval observed after challenge	Horses were observed	d daily for 14 days p	ost-challenge									
Results	See raw data on follo	wing pages.										
	The horses were assessed for the presence of nasal and ocular discharge as signs of respiratory disease. The severity of the combined findings (nasal and ocular discharge) were classified as "mild" or "moderate" according to the following classification:											
	Disease status Nasal score Ocular score											
	Normal = 0	0 or 1	0 or 1									
	Mild = 1	0 or 1	2									
	Mild = 1	1.5, 2, or 3	any									
	Moderate = 2	4 or 6	any									
	Moderate respiratory disease was observed in 8/20 placebo controls and 1/20 vaccinated horse, and mild disease was observed in 12/20 placebo controls and 17/20 vaccinated horses. None of the placebo controls remained healthy following challenge, whereas 2 vaccinates showed no signs of respiratory disease.											
USDA Approval Date	May 31, 2011											

Ocular Discharge:

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I 2	Treatment	Animal	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
3 2	r																2
4 2								2				2					
S I											2				2		2
6 2						2		2	2	2			2	2			
Controls 7 1 2<							2										2
8 2						2								2		2	
9 2							2			2		2	2		2		2
Controls 10 2																	
11 2												2					2
12 1 1 1 1 1 1 1 2 2 2 13 14 2	Controls																
13 13 14 2						2	2	2	2	2	2	2	2		2		2
14 2														2		2	
15 16 2																	
16 2						2				2					2		2
17 2							2	2									
18 2																	
19 2																2	2
20 2						2				2	2		2	2	2		
1 2																2	2
2 2		20				2	2	2	2	2	2	2	2				
3 2													2	2	2		
4 2 2 2 2 2 1 1 2 5 1 1 2 2 1 1 2 1 1 2 1 1 1 2 1		2					2										
5 1 2 2 1 1 2 1 1 2 1		3						2		2	2				2	2	2
6 1 2 2 1 1 1 7 2 2 2 2 2 2 1						2			2			2					
7 1 2		5								2							2
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9 0		7						2	2								
Vaccinates 10 10 2 <t< td=""><td></td><td>8</td><td></td><td></td><td></td><td></td><td>2</td><td>2</td><td>2</td><td>2</td><td></td><td>2</td><td></td><td></td><td></td><td></td><td></td></t<>		8					2	2	2	2		2					
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11 11 12 <	Vasinatas	10							2					2		2	2
13 2	vaccinates	11															
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16 2 2 2 2 2 2 17 2 2 2 2 2 2 2 18 2 2 2 2 2 2 2		15						2	2	1							
18 2 2 2 2										1							
18 2 2 2 2						2			2	2	2		2		2	2	2
		19															

Day Postchallenge

Scoring:

Blank is 0=none 1=mild or moderate 2=severe

Nasal Discharge:

Day Postchallenge

]	Day I	Postcl	naller	ige								
Treatment	Animal	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	1				1	1			1	2	3		3		3	
	2				2	3	3	2	2	3	3	2	4	3	3	2
	3				3	3		2	4			3	3	2	2	
Controls	4					4	4	3	3	4	3	3			2	2
	5					2	3	3	3		3	2	2		2	3
	6						3		2	4	3	3	2	3	2	
	7				1	2	1	2	2	2	2	3	2		2	2
	8								2		2					
	9							2	2	3	2	2	2	3		
Controls	10				3	4	3	3	3	2		2	2	2	2	2
	11															1
	12						3		2	2	2				3	3
	13 3 2 2 2 1 2 2	2														
	14				2	3	4	4	2	4	2	4	3	4	3	
	15				1		3	3	3	3		3	3			2
	16				3	3	3	4	2	4	4	3	4	2	2	2
	17					1		2	2	3	2		3	3		\square
	18				2		3	3	2	2	2	2	3	2	2	2
	19						1	4	2	3		3			2	3
	20				2			2	2		3		2	2	2	
	1								2					2	3	\square
	2															\square
	3									1	2				3	\square
	4				1											\square
	5								2				3			2
	6										3					
	7					1										
	8							2	3	1	3					
	9											1				2
Variation	10										3		2			
vaccinates	11								2							
	12								3	2	3	1	3			2
	13							1	3				2	2	2	
	14									2				2		
	15								2							
	16											1				
	17				2					3				3	2	<u> </u>
	18									4	2		2		2	<u> </u>
	19															<u> </u>
	20								2			3	3			<u> </u>

Scoring:

Blank is 0 = none

1 = slight clear serous, as may be observed in both normal and diseased horses;

1.5 = very slight mucopurulent discharge, one or both nostrils;

2 = moderate clear serous discharge, easily seen in one or both nostrils;

3 = abundant clear serous discharge typically seen only in diseased horses;

4 = moderately mucopurulent, in large quantities in both nostrils;

5 = heavy mucopurulent discharge in large amounts in both nostrils

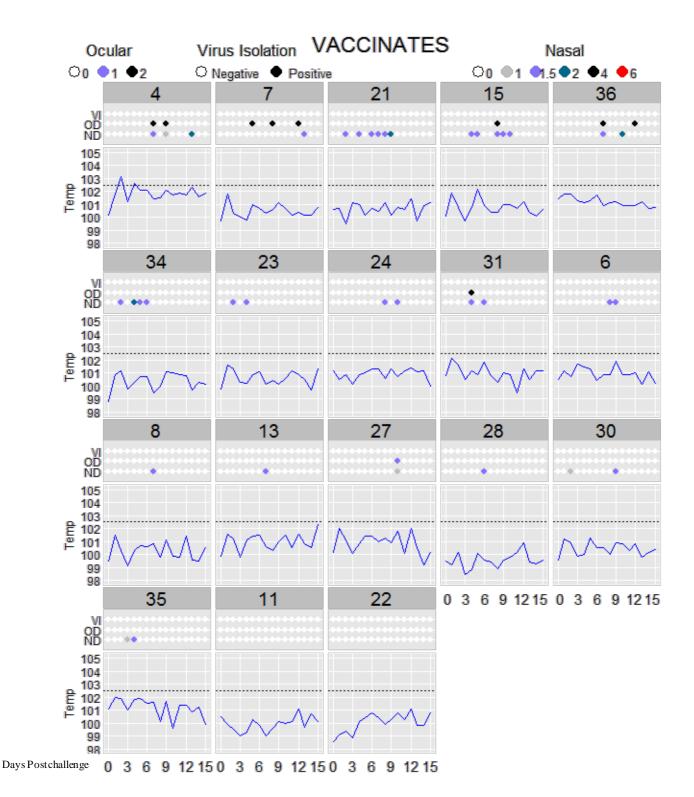
Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of 6-month duration of immunity against
,	respiratory disease caused by equine influenza
Product Administration	Two doses, administered intramuscularly, 21 days apart.
	Vaccinates received test product, and controls received
	adjuvanted diluent.
Study Animals	30 horses (20 vaccinates, 10 controls), 5-6 months of age
Challenge Description	Influenza A/eq/Ohio/2003 administered 184 days post-final
	vaccination
Interval observed after	Horses were observed daily for 10 days post-challenge
challenge	
Results	See tables at the end of document for data.
	 Clinical Signs: An animal was considered positive (affected by challenge) if the animal exhibited: Fever (temperature >102.5°F), OR Nasal discharge (moderate serous discharge or mucopurulent discharge), OR Ocular discharge A total of 9/10 (90%) controls were positive as compared to only 9/20 (45%) vaccinates. There were no adverse reactions to vaccine administration at any timepoint.
USDA Approval Date	September 7, 2010

					D	ays Po	ost-ch	allen	ge			
Treatment	Clinical Sign	0	1	2	3	4	5	6	7	8	9	10
Controls												
	Fever											
1	Nasal discharge						+	+	+	+		
	Ocular discharge						+			+		+
	Fever											
2	Nasal discharge			+			+		+	+	+	
	Ocular discharge						+	+			+	+
	Fever											
3	Nasal discharge							+		+		
	Ocular discharge			+			+			+		+
	Fever											
4	Nasal discharge											
	Ocular discharge						+	+	+			+
	Fever											
5	Nasal discharge					+	+	+	+	+	+	
	Ocular discharge											
	Fever											
6	Nasal discharge					+			+		+	+
	Ocular discharge											+
	Fever											
7	Nasal discharge			+			+		+			+
	Ocular discharge			+				+				
	Fever								+			
8	Nasal discharge						+	+	+			+
	Ocular discharge			+	+		+	+				+
	Fever											
9	Nasal discharge											
	Ocular discharge											
	Fever											
10	Nasal discharge						+	+	+	+	+	
	Ocular discharge					+	+		+	+	+	

					D	ays P	ost-ch	allen	ge			
Treatment	Clinical Sign	0	1	2	3	4	5	6	7	8	9	10
Vaccinates												
	Fever											
1	Nasal discharge											
	Ocular discharge											
	Fever											
2	Nasal discharge											
	Ocular discharge											
	Fever											
3	Nasal discharge											
	Ocular discharge						+			+	+	
	Fever											
4	Nasal discharge								+			
	Ocular discharge											
	Fever											
5	Nasal discharge											
	Ocular discharge											
	Fever											
6	Nasal discharge											
	Ocular discharge											
	Fever											
7	Nasal discharge											
	Ocular discharge											
	Fever											
8	Nasal discharge											
	Ocular discharge											
	Fever											
9	Nasal discharge											
	Ocular discharge											
	Fever						+					
10	Nasal discharge							+	+			
	Ocular discharge									+		+
	Fever											
11	Nasal discharge						+			+	+	+
	Ocular discharge											
	Fever											
12	Nasal discharge									+		
	Ocular discharge						1		1	1		

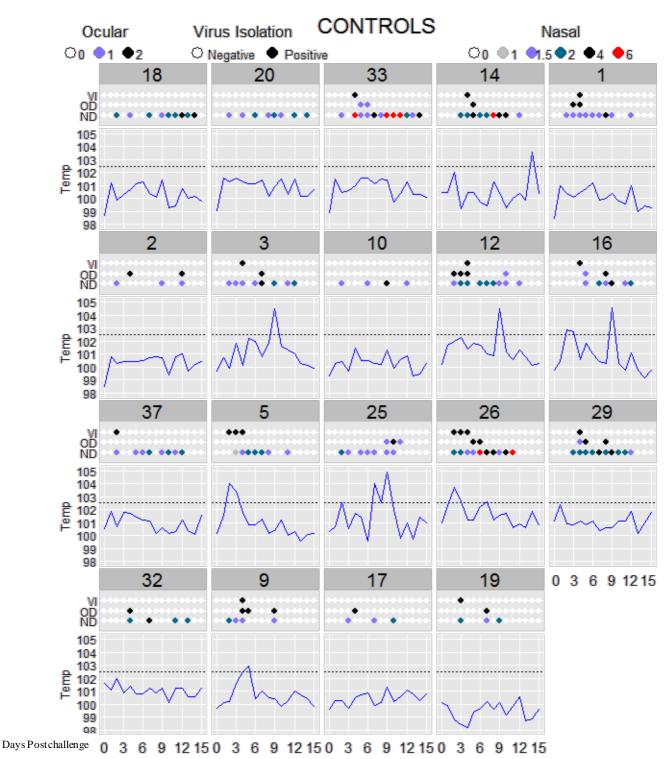
					D	ays P	ost-ch	allen	ge			
Treatment	Clinical Sign	0	1	2	3	4	5	6	7	8	9	10
Vaccinates												
	Fever											
13	Nasal discharge					+						+
	Ocular discharge											
	Fever											
14	Nasal discharge											
	Ocular discharge											
	Fever											
15	Nasal discharge											
	Ocular discharge						+		+			
	Fever											
16	Nasal discharge							+				
	Ocular discharge											
	Fever											
17	Nasal discharge											
	Ocular discharge											
	Fever											
18	Nasal discharge											
	Ocular discharge											
	Fever											
19	Nasal discharge							+		+		
	Ocular discharge											
	Fever											
20	Nasal discharge											
	Ocular discharge											

Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of efficacy against respiratory disease and shedding caused
	by equine influenza
Product	Two doses, administered intramuscularly, 21 days apart.
Administration	
Study Animals	37 horses (18 vaccinates, 19 controls), approximately 9-10 months of age
Challenge	Influenza A/eq/Ohio/2003 administered 3 weeks post-final vaccination
Description	
Interval	Horses were observed, and nasal swabs were collected, daily for 15 days
observed after	post-challenge.
challenge	
Results	See tables at the end of document for data.
	Clinical Signs:
	An animal was considered positive (affected by challenge) if the animal
	exhibited the following at any post-challenge observation point:
	• Fever (temperature $\geq 102.5^{\circ}$ F), OR
	• Ocular discharge, OR
	• Nasal discharge (very slight mucopurulent discharge, or worse)
	Duration of disease was calculated from the date the animal was first observed to be positive to the date of last positive observation for that animal. Based on this calculation, the median duration of disease for the controls was determined to be 11 days as compared to 3 days for the vaccinates.
	Nasal shedding of influenza virus was evaluated through nasal swab virus isolation results. An animal was considered positive if virus was isolated from nasal swabs on one or more occasions following challenge.
	0/18 vaccinates shed virus and 12/19 controls shed virus.
	There were no adverse reactions to vaccine administration at any timepoint.
USDA Approval Date	April 8, 2013



Ocular Discharge: 0=none; 1=mild to moderate; 2=severe

Nasal Discharge: 0=none; 1=slight clear serous, as may be observed in both normal and diseased horses; 1.5=very slight mucopurulent discharge, one or both nostrils; 2=moderate clear serous discharge, easily seen in one or both nostrils; 3=Abundant clear serous discharge typically seen only in diseased horses; 4=moderately mucopurulent, in large quantities in both nostrils; 5=heavy mucopurulent discharge in large amounts in both nostrils



Ocular Discharge: 0=none; 1=mild to moderate; 2=severe

Nasal Discharge: 0=none; 1=slight clear serous, as may be observed in both normal and diseased horses; 1.5=very slight mucopurulent discharge, one or both nostrils; 2=moderate clear serous discharge, easily seen in one or both nostrils; 3=Abundant clear serous discharge typically seen only in diseased horses; 4=moderately mucopurulent, in large quantities in both nostrils; 5=heavy mucopurulent discharge in large amounts in both nostrils

Study Type	Efficacy
Pertaining to	Equine influenza
Study Purpose	Demonstration of efficacy against respiratory disease caused by
	equine influenza A2 strain Richmond 07
Product Administration	Two doses, administered intramuscularly, 21 days apart
Study Animals	20 horses (20 vaccinates), 12 months of age
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	This product class allows the manufacturer to update micro- organisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA- APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
USDA Approval Date	February 2, 2012

Study Type	Efficacy
Pertaining to	Equine influenza
Study Purpose	Demonstration of efficacy against respiratory disease caused by
	equine influenza A2 strain Kentucky 95
Product Administration	Two doses, administered intramuscularly, 21 days apart
Study Animals	20 horses (20 vaccinates), 12 months of age
Challenge Description	Not applicable
Interval observed after	Not applicable
challenge	
Results	This product class allows the manufacturer to update micro- organisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA- APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
USDA Approval Date	February 2, 2012

Study Type	Efficacy						
Pertaining to	West Nile Virus (WNV)						
Study Purpose	Demonstration of twelve month duration of immunity against disease						
	caused by WNV						
Product Administration	Two doses, administered intr	amuscularly, 25 da	ays apart				
Study Animals	30 horses (20 vaccinates, 10	placebo controls) 4	4-5 months of age				
Challenge Description	West Nile Virus was admin	istered at 380 day	ys (10 vaccinated 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 twice	e daily for 14 da	ys post-challenge and				
challenge	once daily for an additiona	l 7 days post-cha	llenge.				
Results	An animal was considered	affected by chall	lenge if it developed				
	neurological disease, as me	easured by morta	lity and microscopic				
	evidence of virus-induced	brain disease (his	stopathology).				
	Animals were also monitor	red for viremia (c	letection of WNV in				
	the blood).	× ×					
	Results are summarized as		1				
	Outcome	Controls	Vaccinates				
	Mortality	7/10 (70%)	1/20 (5%)				
	Viremia at least one day	10/10 (100%)	2/20 (10%)				
	See raw data on following	pages.					
USDA Approval Date	September 3, 2010						

Treatment	#	Died or Euthanized due	Severity Histopat	hological lesions
Treatment	#	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)	6	Yes	2	2
	7	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
	6	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.

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	N = Not recorded; horse was circling with sporadic head / neck tremors.			

Pertaining toWest Nile Virus (WNV)Study PurposeDemonstration of seven month duration of immunity against WNVProduct AdministrationTwo doses, administered intramuscularly 22 days apartStudy Animals30 horses (20 vaccinates, 10 placebo controls) 4-5 months of ageChallenge DescriptionChallenged with West Nile Virus at 201 days (Group 1: 10 vaccinated and 5 placebo control animals) or 222 days (Group 2: 10 vaccinated and 5 placebo control animals) after the second vaccination.Interval observed after challengeHorses were bled on the day of challenge, twice daily for 6 days post-challenge, once daily for an additional 4 days post-challenge, and on day 14 post-challenge	Study Type	Efficient							
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(10 horses)S24NegativeS25NegativeS27NegativeS28NegativeS29NegativePositive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Posi Nega Nega Nega	nd vaccination Group 1 tive tive tive tive tive tive tive tive tive tive tive tive tive tive tive	-			
S25NegativeS27NegativeS28NegativeS29NegativePositive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls (5 horses)	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20	3/10 (30%) is as follows f wing the seco Challenge Posi Posi Posi Posi Posi Nega Nega Nega Nega	nd vaccination Group 1 tive	-			
S27NegativeS28NegativeS29NegativePositive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S20 S22	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Posi Nega Nega Nega Nega Nega Posi	nd vaccinations Group 1 tive tive tive tive tive tive ative ative ative ative ative tive	-			
S28NegativeS29NegativePositive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S24	3/10 (30%) is as follows f wing the seco Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive ative ative ative ative ative ative ative ative ative ative	-			
S29NegativePositive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates	5/5 (100%) e for viremia 201 days follo Horse ID \$\$S16 \$\$S21 \$\$S23 \$\$S26 \$\$S30 \$\$S17 \$\$S18 \$\$S19 \$\$S20 \$\$S22 \$\$S24 \$\$S25	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive a	-			
Positive = WNV detected in blood on one or more occasions post-challenge		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S20 S S22) S24 S25 S27	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive ative ative ative ative ative ative ative ative ative ative ative ative	-			
		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S22 S22 S22 S24 S25 S27 S28	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive a	-			
		1 2 The outcom challenged 2 Controls (5 horses) Vaccinates (10 horses)	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S22 S22 S24 S25 S27 S28 S29	3/10 (30%) is as follows f wing the seco Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive ative	on:			
		1 2 The outcome challenged 2 Controls (5 horses) Vaccinates (10 horses) Positive = W	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S22 S24 S22 S24 S25 S27 S28 S29 NV detected in b	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive ative	post-challenge			
		1 2 The outcome challenged 2 Controls (5 horses) Vaccinates (10 horses) Positive = W	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S22 S24 S22 S24 S25 S27 S28 S29 NV detected in b	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive ative	post-challenge			
		1 2 The outcome challenged 2 Controls (5 horses) Vaccinates (10 horses) Positive = W	5/5 (100%) e for viremia 201 days follo Horse ID S16 S21 S23 S26 S30 S17 S18 S19 S20 S S22 S24 S22 S24 S25 S27 S28 S29 NV detected in b	3/10 (30%) is as follows f wing the secon Challenge Posi Posi Posi Posi Nega Nega Nega Nega Nega Nega Nega Nega	nd vaccinations Group 1 tive tive tive tive tive tive ative	post-challenge			

		• • ·		1				
			as follows for the seco	0 1				
	horses challenged 222 days following the second vaccination:							
		Horse ID	Challenge Group 2					
		S32	Positive					
	Controls	S36	Positive					
	Controls (5 horses)	S39	Positive					
	(5 horses)	S40	Positive					
		S43	Positive					
		S31	Negative					
		S33	Positive					
		S34	Negative					
		S35	Positive					
	Vaccinates	S37	Negative					
	(10 horses)	S38	Negative					
		S41	Negative					
		S42	Negative					
		S44	Negative					
		S45	Positive]				
			od on one or more occasion					
	Negative = WN	V detected in blo	ood on zero occasions post-	challenge				
USDA Approval Date	November 2, 2	009						

Study Type	Safety							
Pertaining to	All fractions							
Study Purpose	To demonstr	ate safety u	nder field condi	itions at th	ree differ	ent test sit	tes	
Product	2 doses given	n intramusc	ularly 21 days a	apart				
Administration								
Study Animals	622 horses vaccinated with two doses including:							
			nonth-old foals					
			month-old foals					
Challenge		1 year or ol	der norses					
Challenge Description	Not Applicat	ble						
Interval	Horses were	observed or	n Days 0, 1 and	3 followi	ng the firs	t vaccinat	ion and	
observed after			wing the second		-			
vaccination	injection site							
Results			reactions obser	ved at any	of the th	ree sites.	Local	
			re summarized					
	N 1 S 1	a.						
	North Dakot	a Site:		Tuon	sient			
	Summary	Total	Number		on Site	Number	Normal	
	juliinu y	Number	with 2 doses	•	lling	1 (unified	i tor mur	
	Age			1 st dose	2 nd dose	1 st dose	2 nd dose	
	2-4 mo	149	149	0	0	149	149	
	5-7 mo	0	0	n/a	n/a	n/a	n/a	
	8-11 mo	0	0	n/a	n/a	n/a	n/a	
	1 yr-5yr	23	23	0	0	23	23	
	6-15 yr	121	121	0	0	121	121	
	>16 yr	3	3	0	0	3	3	
	Total	296	296	0	0	296	296	
	California Si	te:						
		Total	Number		sient			
	Summary	Number	with 2 doses		on Site	Number	Normal	
	Age			1 st dose	lling 2 nd dose	1 st dose	2 nd dose	
	2-4 mo	0	0	n/a	n/a	n/a	n/a	
	5-7 mo	5	5	0	0	5	5	
	8-11 mo	0	0	n/a	n/a	n/a	n/a	
	1 yr-5yr	25	25	0	4	25	21	
	6-15 yr	15	15	0	3	15	12	
	>16 yr	6	6	0	1	6	5	
	Total	51	51	0	8*	51	43	
			were minimal.	The reported	d reactions	were mild,	transient,	
	non-painful in	njection swell	lings.					

	Missouri Site	:						
	Summary	Total Number	Number with 2 doses	Injecti	isient on Site lling	Number Normal		
	Age			1 st dose	2 nd dose	1 st dose	2 nd dose	
	2-4 mo	55	54	0	0	55	54	
	5-7 mo	15	14	0	0	15	14	
	8-11 mo	0	0	n/a	n/a	n/a	n/a	
	1 yr-5yr	134	132	0	0	134	132	
	6-15 yr	68	68	0	0	68	68	
	>16 yr	7	7	0	0	7	7	
	Total	279	275	0	0	279	275	
	Total Across Site	Three Sites: Total Number	Number with 2 doses	Injecti	sient on Site lling	Number Normal		
		Tumber		1 st dose	2 nd dose	1 st dose	2 nd dose	
	North Dakota	296	296	0	0	296	296	
	California	51	51	0	8*	51	43	
	Missouri	279	275	0	0	279	275	
	Total	626	622	0	8*	626	614	
	swellings afte	er the second	were minimal an vaccination in eig actions observed.	ght (8) olde			-	
USDA	February 14,							
Approval Date								

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 Daka									
	Group	Vaccin		Confirmed Pregnant			Parturition Rate			
	1 st trimester product	c/ 143		27			90%			
	1st trimeste placebo	r/ 59	5	4	49	9	91%			
	2 nd trimeste product	r/ 6	6)	6		100%			
	3 rd trimester product	r/ 140	1	17			100% 94%			
	Total – all animals	348	3	604						
	Total – product on	289	2	250	237	9	95%			
	Total – placebo on	59	59 54		49		91%			
	Study 2013-PM-1009 Misssouri Site:									
	Group	Vaccin		onfirmed regnant			arturition ate			
	2011 3 rd trimester	5	5	•B	5		0%			
	2012 1 st trimester	1	1		1	10	0% %			
	2012 2 nd trimester	53	43	3	39	91				
	2012 3 rd trimester	26	26	5	25 96		5%			
	Total – product	85	75	5	70 93		°%0			
	Study 2014-PM-1009 North Dakota Site:									
			Confirm Pregnan		dParturition Rate100%97.1%		FoalsSurvived toEnd ofObservationPeriod51*67			
	2 nd trimester	52	52	52						
	vaccinated 3 rd trimester vaccinated	69	69	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								
	AII UIIEI 10a	is were normal	i anu neaith	y						