



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1525.22
True Name	Equine Rhinopneumonitis Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vetera EHVxp 1/4 - No distributor specified
Date of Compilation Summary	December 11, 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.

Study Type	Efficacy																				
Pertaining to	Equine herpesvirus type 1 (EHV-1)																				
Study Purpose	Demonstration of efficacy against respiratory disease caused by EHV-1																				
Product Administration	Two doses, administered intramuscularly, 21 days apart																				
Study Animals	40 horses (20 vaccinates, 20 controls), 4-5 months of age																				
Challenge Description	Equine herpesvirus type 1 administered 15 days post-final vaccination																				
Interval observed after challenge	Horses were observed daily for 14 days post-challenge																				
Results	<p>See raw data on following pages.</p> <p>The horses were assessed for the presence of nasal discharge as signs of respiratory disease. The severity of nasal discharge was classified as “normal”, “mild”, or “moderate” according to the following classification of the nasal scores.</p> <table border="1"> <thead> <tr> <th>Disease status</th> <th>MaximumNasal Score</th> </tr> </thead> <tbody> <tr> <td>Normal</td> <td>0 or 1</td> </tr> <tr> <td>Mild</td> <td>1.5 or 2</td> </tr> <tr> <td>Moderate</td> <td>4 or 6</td> </tr> </tbody> </table> <p>The number of horses in each category were:</p> <table border="1"> <thead> <tr> <th></th> <th>Normal</th> <th>Mild</th> <th>Moderate</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>0</td> <td>10</td> <td>10</td> </tr> <tr> <td>Vaccine</td> <td>6</td> <td>11</td> <td>3</td> </tr> </tbody> </table>	Disease status	MaximumNasal Score	Normal	0 or 1	Mild	1.5 or 2	Moderate	4 or 6		Normal	Mild	Moderate	Control	0	10	10	Vaccine	6	11	3
Disease status	MaximumNasal Score																				
Normal	0 or 1																				
Mild	1.5 or 2																				
Moderate	4 or 6																				
	Normal	Mild	Moderate																		
Control	0	10	10																		
Vaccine	6	11	3																		
USDA Approval Date	January 28, 2009																				

Nasal Discharge:

Day Postchallenge

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

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 type 4 (EHV-4)															
Study Purpose	Demonstration of efficacy against respiratory disease caused by EHV-4															
Product Administration	Two doses, administered intramuscularly, 21 days apart															
Study Animals	40 horses (20 vaccinates, 20 controls), 4 months of age															
Challenge Description	Equine herpesvirus type 4 administered 14 days post-final vaccination															
Interval observed after challenge	Horses were observed daily for 14 days post-challenge															
Results	<p>See raw data on following pages.</p> <p>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:</p> <table border="1"> <thead> <tr> <th>Disease status</th> <th>Nasal score</th> <th>Ocular score</th> </tr> </thead> <tbody> <tr> <td>Normal = 0</td> <td>0 or 1</td> <td>0 or 1</td> </tr> <tr> <td>Mild = 1</td> <td>0 or 1</td> <td>2</td> </tr> <tr> <td>Mild = 1</td> <td>1.5, 2, or 3</td> <td>any</td> </tr> <tr> <td>Moderate = 2</td> <td>4 or 6</td> <td>any</td> </tr> </tbody> </table> <p>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.</p> <p>None of the placebo controls remained healthy following challenge, whereas 2 vaccinates showed no signs of respiratory disease.</p>	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
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														
USDA Approval Date	May 31, 2011															

Ocular Discharge:

		Day Postchallenge														
Treatment	Animal	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
I	1								2		2	2	2		2	2
	2				2	2	2	2	2	2	2	2	2	2	2	
	3				2	2		2	2	2		2	2	2	2	2
	4				2	2	2	2	2		2	2	2		2	
	5					2					2			2	2	2
	6				2		2	2	2	2	2	2	2	2	2	
	7					2	2	2	2	2	2	2		2		2
	8				2		2	2		2						
	9				2	2	2	2	2	2	2	2	2	2	2	2
	10				2	2	2	2	2	2		2	2	2	2	2
	11				2	2	2	2	2	2	2	2	2	2	2	2
	12												2		2	
	13															
	14				2	2	2	2	2		2	2	2	2		2
	15					2	2	2		2	2	2	2			
	16							2		2	2	2	2			
	17					2		2		2	2	2	2	2	2	2
	18				2	2	2	2	2	2	2	2	2	2		
	19				2	2	2	2			2				2	2
	20				2	2	2	2	2	2	2	2	2			
Vaccinates	1											2	2	2		
	2					2										
	3						2		2	2				2	2	2
	4				2			2			2					
	5								2							2
	6									2	2					
	7						2	2								
	8					2	2	2	2		2					
	9															2
	10							2					2		2	2
	11															
	12										2	2	2			2
	13					2	2		2					2	2	2
	14															
	15						2	2								
	16															
	17				2			2	2	2		2		2	2	2
	18									2		2		2	2	
	19															
	20															

Scoring:

Blank is 0=none

1=mild or moderate

2=severe

Nasal Discharge:

Day Postchallenge

		Day Postchallenge															
Treatment	Animal	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	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		
	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			
	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	2	1	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				
	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		
Vaccinates	1								2					2	3		
	2																
	3									1	2				3		
	4				1												
	5								2				3			2	
	6										3						
	7					1											
	8							2	3	1	3						
	9											1				2	
	10										3		2				
	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		
	18									4	2		2		2		
	19																
	20								2			3	3				

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	Safety																																																																																																																																											
Pertaining to	All fractions																																																																																																																																											
Study Purpose	To demonstrate safety under field conditions at three different test sites																																																																																																																																											
Product Administration	2 doses given intramuscularly 21 days apart																																																																																																																																											
Study Animals	622 horses vaccinated with two doses including: <ul style="list-style-type: none"> • 203-two to four month-old foals • 19-five to seven month-old foals • 400-1 year or older horses 																																																																																																																																											
Challenge Description	Not Applicable																																																																																																																																											
Interval observed after vaccination	Horses were observed on Days 0, 1 and 3 following the first vaccination and on Days 1, 3 and 7 following the second vaccination for systemic and local injection site reactions.																																																																																																																																											
Results	<p>There were no systemic reactions observed at any of the three sites. Local injection site reactions are summarized below.</p> <p>North Dakota Site:</p> <table border="1"> <thead> <tr> <th rowspan="2">Summary</th> <th rowspan="2">Total Number</th> <th rowspan="2">Number with 2 doses</th> <th colspan="2">Transient Injection Site Swelling</th> <th colspan="2">Number Normal</th> </tr> <tr> <th>1st dose</th> <th>2nd dose</th> <th>1st dose</th> <th>2nd dose</th> </tr> </thead> <tbody> <tr> <td>Age</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2-4 mo</td> <td>149</td> <td>149</td> <td>0</td> <td>0</td> <td>149</td> <td>149</td> </tr> <tr> <td>5-7 mo</td> <td>0</td> <td>0</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> </tr> <tr> <td>8-11 mo</td> <td>0</td> <td>0</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> </tr> <tr> <td>1 yr-5yr</td> <td>23</td> <td>23</td> <td>0</td> <td>0</td> <td>23</td> <td>23</td> </tr> <tr> <td>6-15 yr</td> <td>121</td> <td>121</td> <td>0</td> <td>0</td> <td>121</td> <td>121</td> </tr> <tr> <td>>16 yr</td> <td>3</td> <td>3</td> <td>0</td> <td>0</td> <td>3</td> <td>3</td> </tr> <tr> <td>Total</td> <td>296</td> <td>296</td> <td>0</td> <td>0</td> <td>296</td> <td>296</td> </tr> </tbody> </table> <p>California Site:</p> <table border="1"> <thead> <tr> <th rowspan="2">Summary</th> <th rowspan="2">Total Number</th> <th rowspan="2">Number with 2 doses</th> <th colspan="2">Transient Injection Site Swelling</th> <th colspan="2">Number Normal</th> </tr> <tr> <th>1st dose</th> <th>2nd dose</th> <th>1st dose</th> <th>2nd dose</th> </tr> </thead> <tbody> <tr> <td>Age</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2-4 mo</td> <td>0</td> <td>0</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> </tr> <tr> <td>5-7 mo</td> <td>5</td> <td>5</td> <td>0</td> <td>0</td> <td>5</td> <td>5</td> </tr> <tr> <td>8-11 mo</td> <td>0</td> <td>0</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> </tr> <tr> <td>1 yr-5yr</td> <td>25</td> <td>25</td> <td>0</td> <td>4</td> <td>25</td> <td>21</td> </tr> <tr> <td>6-15 yr</td> <td>15</td> <td>15</td> <td>0</td> <td>3</td> <td>15</td> <td>12</td> </tr> <tr> <td>>16 yr</td> <td>6</td> <td>6</td> <td>0</td> <td>1</td> <td>6</td> <td>5</td> </tr> <tr> <td>Total</td> <td>51</td> <td>51</td> <td>0</td> <td>8*</td> <td>51</td> <td>43</td> </tr> </tbody> </table> <p>*Postvaccination reactions were minimal. The reported reactions were mild, transient, non-painful injection swellings.</p>						Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal		1 st dose	2 nd dose	1 st dose	2 nd dose	Age							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	Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal		1 st dose	2 nd dose	1 st dose	2 nd dose	Age							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
Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal																																																																																																																																							
			1 st dose	2 nd dose	1 st dose	2 nd dose																																																																																																																																						
Age																																																																																																																																												
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																																																																																																																																						
Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal																																																																																																																																							
			1 st dose	2 nd dose	1 st dose	2 nd dose																																																																																																																																						
Age																																																																																																																																												
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																																																																																																																																						

	Missouri Site:						
	Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		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 Three Sites:						
	Site	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal	
				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	
*Postvaccination reactions were minimal and described as mild, transient, non-painful swellings after the second vaccination in eight (8) older, heavily vaccinated horses. There were no systemic reactions observed.							
USDA Approval Date	February 14, 2012						

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety in pregnant mares under field conditions at two different test sites
Product Administration	Two intramuscular doses, given 16-28 days apart. 54 pregnant mares 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 Description	Not applicable
Interval observed after vaccination	1 st and 2 nd trimester: Mares observed immediately 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					
	<i>North Dakota Site:</i>					
	Group	Vaccinated	Confirmed Pregnant	Foals	Parturition Rate	
	1 st trimester/ product	143	127	114	90%	
	1st trimester/ placebo	59	54	49	91%	
	2 nd trimester/ product	6	6	6	100%	
	3 rd trimester/ product	140	117	117	100%	
	Total – all animals	348	304	286	94%	
	Total – product only	289	250	237	95%	
	Total – placebo only	59	54	49	91%	
	Study 2013-PM-1009					
	<i>Missouri Site:</i>					
	Group	Vaccinated	Confirmed Pregnant	Foals	Parturition Rate	
	2011 3 rd trimester	5	5	5	100%	
	2012 1 st trimester	1	1	1	100%	
2012 2 nd trimester	53	43	39	91%		
2012 3 rd trimester	26	26	25	96%		
Total – product	85	75	70	93%		
Study 2014-PM-1009						
<i>North Dakota Site:</i>						
Group	Vaccinated	Confirmed Pregnant	Foaled	Parturition Rate	Foals Survived to End of Observation Period	
2 nd trimester vaccinated	52	52	52	100%	51*	
3 rd trimester vaccinated	69	69	67**	97.1%	67	
*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 cooperator.						
All other foals were normal and healthy						
USDA Approval Date	September 12, 2014					