



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA 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	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.**

<b>Study Type</b>	Efficacy																				
<b>Pertaining to</b>	Equine herpesvirus type 1 (EHV-1)																				
<b>Study Purpose</b>	Demonstration of efficacy against respiratory disease caused by EHV-1																				
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart																				
<b>Study Animals</b>	40 horses (20 vaccinates, 20 controls), 4-5 months of age																				
<b>Challenge Description</b>	Equine herpesvirus type 1 administered 15 days post-final vaccination																				
<b>Interval observed after challenge</b>	Horses were observed daily for 14 days post-challenge																				
<b>Results</b>	<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>Maximum Nasal 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><b>Control</b></td> <td>0</td> <td>10</td> <td>10</td> </tr> <tr> <td><b>Vaccine</b></td> <td>6</td> <td>11</td> <td>3</td> </tr> </tbody> </table>	Disease status	Maximum Nasal Score	Normal	0 or 1	Mild	1.5 or 2	Moderate	4 or 6		Normal	Mild	Moderate	<b>Control</b>	0	10	10	<b>Vaccine</b>	6	11	3
Disease status	Maximum Nasal Score																				
Normal	0 or 1																				
Mild	1.5 or 2																				
Moderate	4 or 6																				
	Normal	Mild	Moderate																		
<b>Control</b>	0	10	10																		
<b>Vaccine</b>	6	11	3																		
<b>USDA Approval Date</b>	January 28, 2009																				

**Nasal Discharge:**

Day Postchallenge

Treatment	ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
<b>Controls (20 horses)</b>	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	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	
<b>Vaccinates (20 horses)</b>	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

<b>Study Type</b>	Efficacy															
<b>Pertaining to</b>	Equine herpesvirus type 4 (EHV-4)															
<b>Study Purpose</b>	Demonstration of efficacy against respiratory disease caused by EHV-4															
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart															
<b>Study Animals</b>	40 horses (20 vaccinates, 20 controls), 4 months of age															
<b>Challenge Description</b>	Equine herpesvirus type 4 administered 14 days post-final vaccination															
<b>Interval observed after challenge</b>	Horses were observed daily for 14 days post-challenge															
<b>Results</b>	<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><b>Disease status</b></th> <th><b>Nasal score</b></th> <th><b>Ocular score</b></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>	<b>Disease status</b>	<b>Nasal score</b>	<b>Ocular score</b>	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
<b>Disease status</b>	<b>Nasal score</b>	<b>Ocular score</b>														
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														
<b>USDA Approval Date</b>	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          <b>Controls</b>	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	2	
	7					2	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	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	2
	12													2		2	
	13																
	14				2	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	2
	18				2	2	2	2	2	2	2	2	2	2	2		
	19				2	2	2	2	2			2				2	2
	20				2	2	2	2	2	2	2	2	2				
<b>Vaccinates</b>	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
<b>Controls</b>	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	
<b>Vaccinates</b>	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

<b>Study Type</b>	Safety																																																																																																																																											
<b>Pertaining to</b>	All fractions																																																																																																																																											
<b>Study Purpose</b>	To demonstrate safety under field conditions at three different test sites																																																																																																																																											
<b>Product Administration</b>	2 doses given intramuscularly 21 days apart																																																																																																																																											
<b>Study Animals</b>	622 horses vaccinated with two doses including: <ul style="list-style-type: none"> <li>• 203-two to four month-old foals</li> <li>• 19-five to seven month-old foals</li> <li>• 400-1 year or older horses</li> </ul>																																																																																																																																											
<b>Challenge Description</b>	Not Applicable																																																																																																																																											
<b>Interval observed after vaccination</b>	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.																																																																																																																																											
<b>Results</b>	<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>1<sup>st</sup> dose</th> <th>2<sup>nd</sup> dose</th> <th>1<sup>st</sup> dose</th> <th>2<sup>nd</sup> 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>&gt;16 yr</td> <td>3</td> <td>3</td> <td>0</td> <td>0</td> <td>3</td> <td>3</td> </tr> <tr> <td><b>Total</b></td> <td><b>296</b></td> <td><b>296</b></td> <td><b>0</b></td> <td><b>0</b></td> <td><b>296</b></td> <td><b>296</b></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>1<sup>st</sup> dose</th> <th>2<sup>nd</sup> dose</th> <th>1<sup>st</sup> dose</th> <th>2<sup>nd</sup> 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>&gt;16 yr</td> <td>6</td> <td>6</td> <td>0</td> <td>1</td> <td>6</td> <td>5</td> </tr> <tr> <td><b>Total</b></td> <td><b>51</b></td> <td><b>51</b></td> <td><b>0</b></td> <td><b>8*</b></td> <td><b>51</b></td> <td><b>43</b></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 <sup>st</sup> dose	2 <sup>nd</sup> dose	1 <sup>st</sup> dose	2 <sup>nd</sup> 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	<b>Total</b>	<b>296</b>	<b>296</b>	<b>0</b>	<b>0</b>	<b>296</b>	<b>296</b>	Summary	Total Number	Number with 2 doses	Transient Injection Site Swelling		Number Normal		1 <sup>st</sup> dose	2 <sup>nd</sup> dose	1 <sup>st</sup> dose	2 <sup>nd</sup> 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	<b>Total</b>	<b>51</b>	<b>51</b>	<b>0</b>	<b>8*</b>	<b>51</b>	<b>43</b>
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1 yr-5yr	23	23	0	0	23	23																																																																																																																																						
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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																																																																																																																																						
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<b>USDA Approval Date</b>	Missouri Site:						
	<b>Summary</b>	<b>Total Number</b>	<b>Number with 2 doses</b>	<b>Transient Injection Site Swelling</b>		<b>Number Normal</b>	
	Age			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	1 <sup>st</sup> dose	2 <sup>nd</sup> 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
	<b>Total</b>	<b>279</b>	<b>275</b>	<b>0</b>	<b>0</b>	<b>279</b>	<b>275</b>
	Total Across Three Sites:						
	<b>Site</b>	<b>Total Number</b>	<b>Number with 2 doses</b>	<b>Transient Injection Site Swelling</b>		<b>Number Normal</b>	
				1 <sup>st</sup> dose	2 <sup>nd</sup> dose	1 <sup>st</sup> dose	2 <sup>nd</sup> dose
	North Dakota	296	296	0	0	296	296
California	51	51	0	8*	51	43	
Missouri	279	275	0	0	279	275	
<b>Total</b>	<b>626</b>	<b>622</b>	<b>0</b>	<b>8*</b>	<b>626</b>	<b>614</b>	
*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.							
February 14, 2012							



<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety in pregnant mares under field conditions at two different test sites
<b>Product Administration</b>	Two intramuscular doses, given 16-28 days apart. 54 pregnant mares were injected with placebo and 325 pregnant mares were vaccinated with test product.
<b>Study Animals</b>	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.
<b>Challenge Description</b>	Not applicable
<b>Interval observed after vaccination</b>	1 <sup>st</sup> and 2 <sup>nd</sup> 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 <sup>rd</sup> trimester: Mares observed immediately after vaccination and daily for overall health and for abortion. Resulting foals were observed daily for 30 days following birth.
<b>Results</b>	Results shown on next page

**Results****Study 2013-PM-1009****North Dakota Site:**

<b>Group</b>	<b>Vaccinated</b>	<b>Confirmed Pregnant</b>	<b>Foals</b>	<b>Parturition Rate</b>
1 <sup>st</sup> trimester/ product	143	127	114	90%
1st trimester/ placebo	59	54	49	91%
2 <sup>nd</sup> trimester/ product	6	6	6	100%
3 <sup>rd</sup> trimester/ product	140	117	117	100%
<b>Total – all animals</b>	<b>348</b>	<b>304</b>	<b>286</b>	<b>94%</b>
<b>Total – product only</b>	<b>289</b>	<b>250</b>	<b>237</b>	<b>95%</b>
<b>Total – placebo only</b>	<b>59</b>	<b>54</b>	<b>49</b>	<b>91%</b>

**Study 2013-PM-1009****Missouri Site:**

<b>Group</b>	<b>Vaccinated</b>	<b>Confirmed Pregnant</b>	<b>Foals</b>	<b>Parturition Rate</b>
2011 3 <sup>rd</sup> trimester	5	5	5	100%
2012 1 <sup>st</sup> trimester	1	1	1	100%
2012 2 <sup>nd</sup> trimester	53	43	39	91%
2012 3 <sup>rd</sup> trimester	26	26	25	96%
<b>Total – product</b>	<b>85</b>	<b>75</b>	<b>70</b>	<b>93%</b>

**Study 2014-PM-1009****North Dakota Site:**

<b>Group</b>	<b>Vaccinated</b>	<b>Confirmed Pregnant</b>	<b>Foaled</b>	<b>Parturition Rate</b>	<b>Foals Survived to End of Observation Period</b>
2 <sup>nd</sup> trimester vaccinated	52	52	52	100%	51*
3 <sup>rd</sup> 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