



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1505.22
True Name	Equine Influenza Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vetera EIVxp - No distributor specified
Date of Compilation Summary	February 06, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

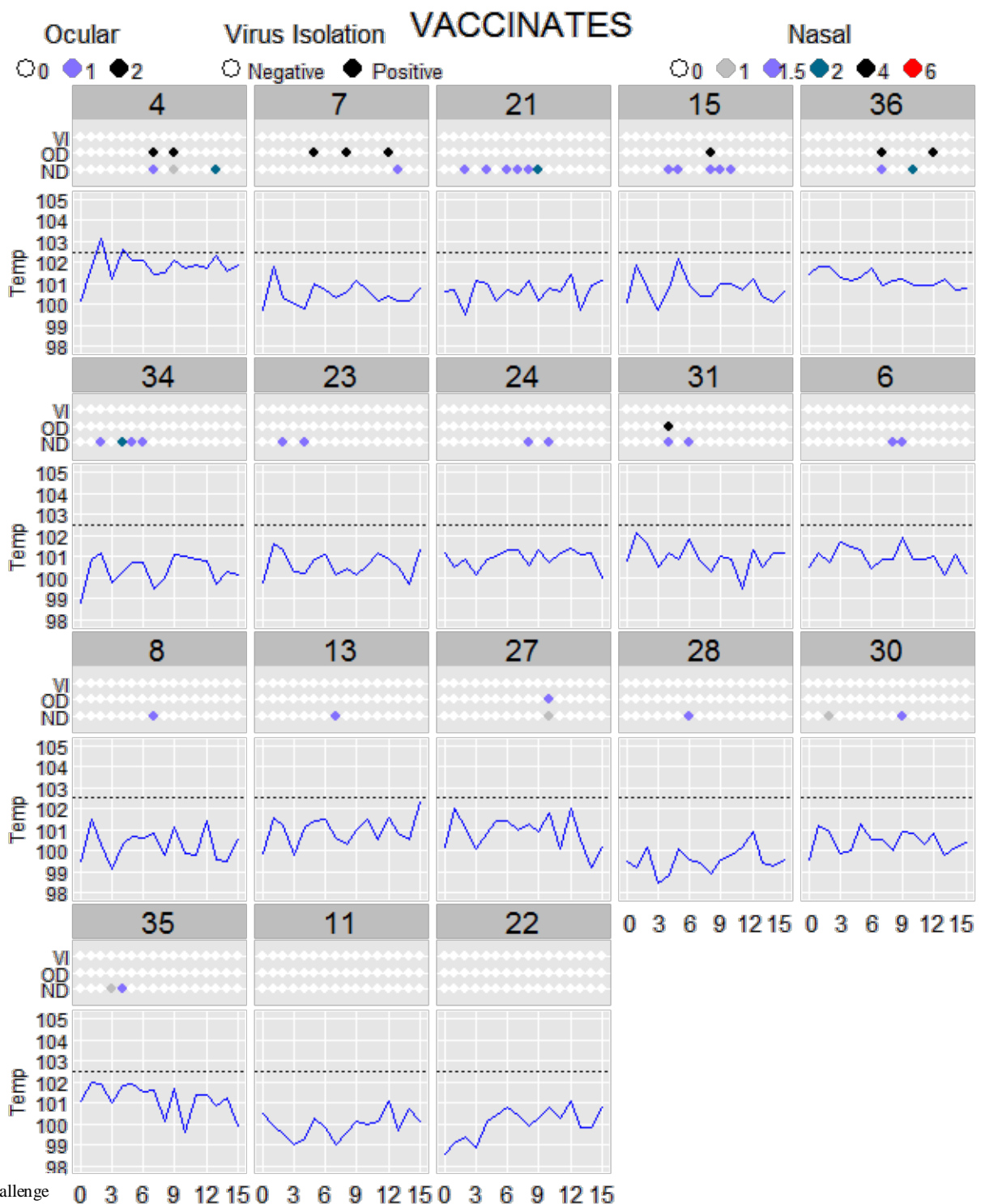
<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza virus
<b>Study Purpose</b>	Demonstration of 6-month duration of immunity against respiratory disease caused by equine influenza
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart. Vaccinates received test product, and controls received adjuvanted diluent.
<b>Study Animals</b>	30 horses (20 vaccinates, 10 controls), 5-6 months of age
<b>Challenge Description</b>	Influenza A/eq/Ohio/2003 administered 184 days post-final vaccination
<b>Interval observed after challenge</b>	Horses were observed daily for 10 days post-challenge
<b>Results</b>	<p><b>See tables at the end of document for data.</b></p> <p><b>Clinical Signs:</b> An animal was considered positive (affected by challenge) if the animal exhibited:</p> <ul style="list-style-type: none"> <li>• Fever (temperature &gt;102.5°F), OR</li> <li>• Nasal discharge (moderate serous discharge or mucopurulent discharge), OR</li> <li>• Ocular discharge</li> </ul> <p>A total of 9/10 (90%) controls were positive as compared to only 9/20 (45%) vaccinates.</p> <p>There were no adverse reactions to vaccine administration at any timepoint.</p>
<b>USDA Approval Date</b>	September 7, 2010

Treatment	Clinical Sign	Days Post-challenge										
		0	1	2	3	4	5	6	7	8	9	10
<b>Controls</b>												
1	Fever											
	Nasal discharge							+	+	+	+	
	Ocular discharge							+			+	+
2	Fever											
	Nasal discharge			+				+		+	+	+
	Ocular discharge							+	+			+
3	Fever											
	Nasal discharge								+		+	
	Ocular discharge			+				+			+	+
4	Fever											
	Nasal discharge											
	Ocular discharge							+	+	+		+
5	Fever											
	Nasal discharge						+	+	+	+	+	
	Ocular discharge											
6	Fever											
	Nasal discharge						+			+		+
	Ocular discharge											+
7	Fever											
	Nasal discharge			+				+		+		+
	Ocular discharge			+					+			
8	Fever									+		
	Nasal discharge							+	+	+		+
	Ocular discharge			+	+			+	+			+
9	Fever											
	Nasal discharge											
	Ocular discharge											
10	Fever											
	Nasal discharge							+	+	+	+	+
	Ocular discharge						+	+		+	+	+

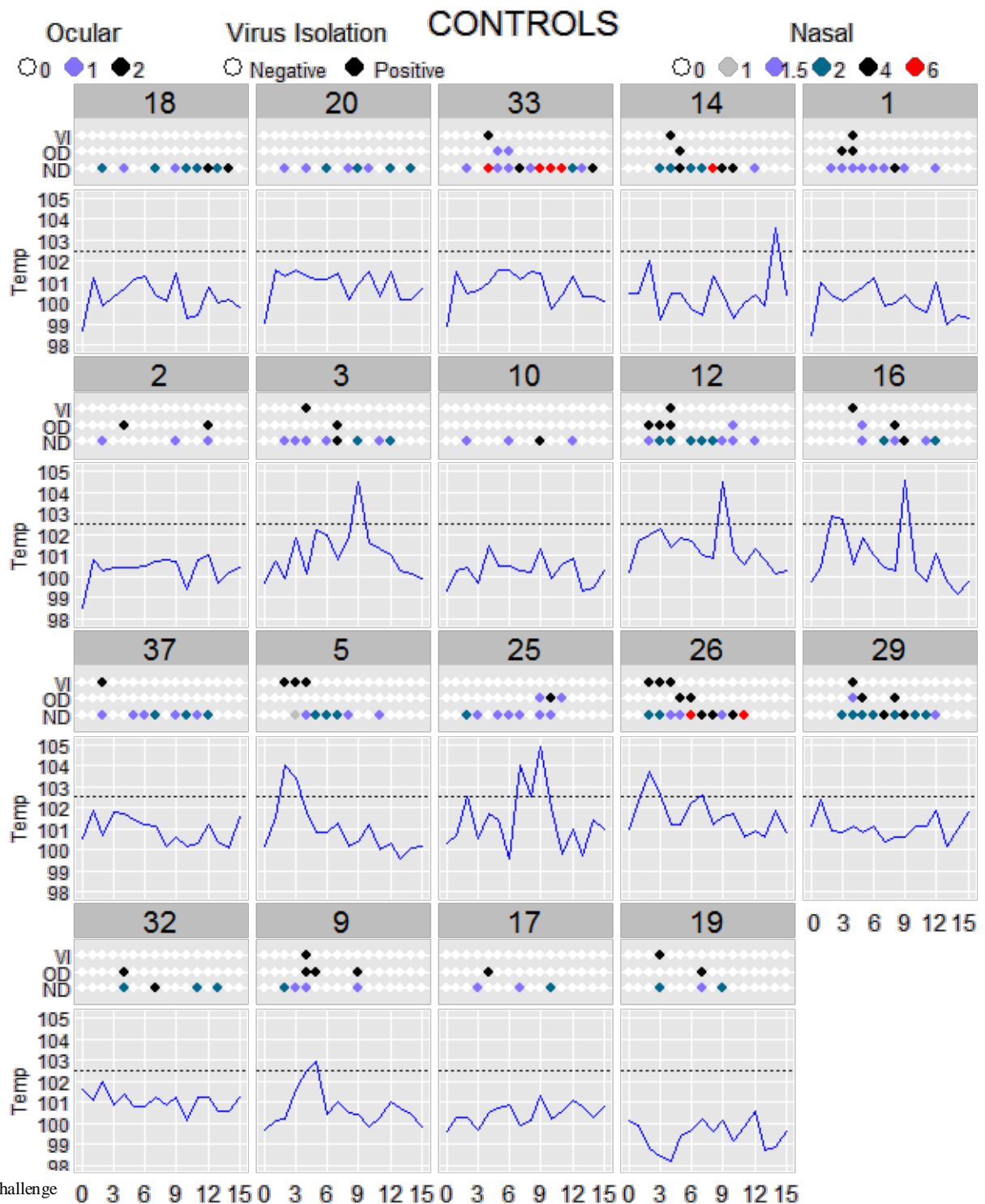
Treatment	Clinical Sign	Days Post-challenge												
		0	1	2	3	4	5	6	7	8	9	10		
<b>Vaccinates</b>														
1	Fever													
	Nasal discharge													
	Ocular discharge													
2	Fever													
	Nasal discharge													
	Ocular discharge													
3	Fever													
	Nasal discharge													
	Ocular discharge							+			+	+		
4	Fever													
	Nasal discharge									+				
	Ocular discharge													
5	Fever													
	Nasal discharge													
	Ocular discharge													
6	Fever													
	Nasal discharge													
	Ocular discharge													
7	Fever													
	Nasal discharge													
	Ocular discharge													
8	Fever													
	Nasal discharge													
	Ocular discharge													
9	Fever													
	Nasal discharge													
	Ocular discharge													
10	Fever							+						
	Nasal discharge								+	+				
	Ocular discharge										+		+	
11	Fever													
	Nasal discharge							+			+	+	+	
	Ocular discharge													
12	Fever													
	Nasal discharge										+			
	Ocular discharge													

Treatment	Clinical Sign	Days Post-challenge										
		0	1	2	3	4	5	6	7	8	9	10
<b>Vaccinates</b>												
13	Fever											
	Nasal discharge						+					+
	Ocular discharge											
14	Fever											
	Nasal discharge											
	Ocular discharge											
15	Fever											
	Nasal discharge											
	Ocular discharge							+		+		
16	Fever											
	Nasal discharge								+			
	Ocular discharge											
17	Fever											
	Nasal discharge											
	Ocular discharge											
18	Fever											
	Nasal discharge											
	Ocular discharge											
19	Fever											
	Nasal discharge								+		+	
	Ocular discharge											
20	Fever											
	Nasal discharge											
	Ocular discharge											

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza virus
<b>Study Purpose</b>	Demonstration of efficacy against respiratory disease and shedding caused by equine influenza
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart.
<b>Study Animals</b>	37 horses (18 vaccinates, 19 controls), approximately 9-10 months of age
<b>Challenge Description</b>	Influenza A/eq/Ohio/2003 administered 3 weeks post-final vaccination
<b>Interval observed after challenge</b>	Horses were observed, and nasal swabs were collected, daily for 15 days post-challenge.
<b>Results</b>	<p><b>See tables at the end of document for data.</b></p> <p><b>Clinical Signs:</b>  An animal was considered positive (affected by challenge) if the animal exhibited the following at any post-challenge observation point:</p> <ul style="list-style-type: none"> <li>• Fever (temperature <math>\geq 102.5^{\circ}\text{F}</math>), OR</li> <li>• Ocular discharge, OR</li> <li>• Nasal discharge (very slight mucopurulent discharge, or worse)</li> </ul> <p><b>Duration</b> 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.</p> <p><b>Nasal shedding</b> 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.</p> <p>0/18 vaccinates shed virus and 12/19 controls shed virus.</p> <p>There were no adverse reactions to vaccine administration at any timepoint.</p>
<b>USDA Approval Date</b>	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

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<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza
<b>Study Purpose</b>	Demonstration of efficacy against respiratory disease caused by equine influenza A2 strain Richmond 07
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart
<b>Study Animals</b>	20 horses (20 vaccinates), 12 months of age
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	Not applicable
<b>Results</b>	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.
<b>USDA Approval Date</b>	February 2, 2012

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza
<b>Study Purpose</b>	Demonstration of efficacy against respiratory disease caused by equine influenza A2 strain Kentucky 95
<b>Product Administration</b>	Two doses, administered intramuscularly, 21 days apart
<b>Study Animals</b>	20 horses (20 vaccinates), 12 months of age
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	Not applicable
<b>Results</b>	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.
<b>USDA Approval Date</b>	February 2, 2012

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<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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	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.							
<b>USDA Approval Date</b>	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