



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	4845.33
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prestige 5 - Merck Animal Health
Date of Compilation Summary	September 17, 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.

Study Type	Efficacy		
Pertaining to	<i>Clostridium tetani</i>		
Study Purpose	Demonstrate efficacy against <i>C. tetani</i>		
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 challenge	Six weeks after vaccination, guinea pigs were bled for serological testing.		
Results	<p>Efficacy of <i>C. tetani</i> was demonstrated in laboratory animals according to 9CFR 113.114(c).</p> <p>Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool.</p> <table border="1" data-bbox="580 920 991 1037"> <tr> <td style="text-align: center;">Pooled Guinea Pig Antitoxin titer (A.U./mL)</td> </tr> <tr> <td style="text-align: center;">2.082</td> </tr> </table>	Pooled Guinea Pig Antitoxin titer (A.U./mL)	2.082
Pooled Guinea Pig Antitoxin titer (A.U./mL)			
2.082			
USDA Approval Date	June 15, 2010		

Study Type	Efficacy								
Pertaining to	Eastern Equine Encephalomyelitis (EEE)								
Study Purpose	Demonstrate efficacy against EEE								
Product Administration	Two doses administered intramuscularly 3 weeks apart.								
Study Animals	Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g								
Challenge Description	Not applicable								
Interval observed after challenge	14 days post 2nd vaccination, guinea pigs were bled for serological testing.								
Results	<p>Efficacy of EEE was demonstrated in laboratory animals according to 9CFR 113.207(b).</p> <p>Satisfactory test result is a Virus Neutralization Titer of $\geq 1:40$ in at least 9 out of 10 vaccinates (2nd stage - at least 17 out of 20 vaccinates).</p> <table border="1" data-bbox="579 920 1254 1072"> <thead> <tr> <th>Treatment group</th> <th>Results</th> <th>Test Disposition</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>17/20 $\geq 1:40$</td> <td rowspan="2">Satisfactory</td> </tr> <tr> <td>Controls</td> <td>2/2 $<1:4$</td> </tr> </tbody> </table>	Treatment group	Results	Test Disposition	Vaccinates	17/20 $\geq 1:40$	Satisfactory	Controls	2/2 $<1:4$
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Vaccinates	17/20 $\geq 1:40$	Satisfactory							
Controls	2/2 $<1:4$								
USDA Approval Date	June 15, 2010								

Study Type	Efficacy								
Pertaining to	Western Equine Encephalomyelitis (WEE)								
Study Purpose	Demonstrate efficacy against WEE								
Product Administration	Two doses administered intramuscularly 3 weeks apart.								
Study Animals	Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g								
Challenge Description	Not applicable								
Interval observed after challenge	14 days post 2nd vaccination, guinea pigs were bled for serological testing.								
Results	<p>Efficacy of WEE was demonstrated in laboratory animals according to 9CFR 113.207(b).</p> <p>Satisfactory test result is a Virus Neutralization Titer of $\geq 1:40$ in at least 9 of the vaccinates.</p> <table border="1" data-bbox="587 884 1259 1037"> <thead> <tr> <th>Treatment group</th> <th>Results</th> <th>Test Disposition</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>9/10 $\geq 1:40$</td> <td rowspan="2">Satisfactory</td> </tr> <tr> <td>Controls</td> <td>2/2 $<1:4$</td> </tr> </tbody> </table>	Treatment group	Results	Test Disposition	Vaccinates	9/10 $\geq 1:40$	Satisfactory	Controls	2/2 $<1:4$
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USDA Approval Date	June 15, 2010								

Study Type	Efficacy																																
Pertaining to	Equine Herpesvirus-Subtype 1 (EHV-1), DA35 strain																																
Study Purpose	Efficacy against respiratory disease caused by EHV-1																																
Product Administration	Two doses, administered intramuscularly, 21 days apart.																																
Study Animals	16 vaccinates and 16 placebo-vaccinated controls, seronegative to EHV-1. Horses were 11 months of age, mixed sex.																																
Challenge Description	Horses were challenged with EHV-1, 23 days post second vaccination.																																
Interval observed after challenge	Observed for 14 days post challenge for clinical signs of respiratory disease.																																
Results	<p>Animals displaying clinical signs were considered to be affected by the challenge. Result summaries below.</p> <p>Body Temperatures $\geq 102.5^{\circ}\text{F}$ were considered to be elevated.</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Hyperthermia Affected</td> <td>15/16 or 94%</td> <td>16/16 or 100%</td> </tr> </tbody> </table> <p>Observations of nasal discharged were scored as: 0 - Normal 1 - Very Mild 2 - Moderate 3 - Severe</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th></th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Nasal Discharge</td> <td>Mildly Affected</td> <td>5/16 or 31%</td> <td>1/16 or 6%</td> </tr> <tr> <td>Moderately Affected</td> <td>7/16 or 44%</td> <td>2/16 or 13%</td> </tr> <tr> <td>Severely Affected</td> <td>4/16 or 25%</td> <td>13/16 or 80%</td> </tr> </tbody> </table> <p>Observations of coughing were scored as: 0 - No coughing or coughed once 2 - Coughed twice 3 - Coughed three times or more Animals were scored as a 2 or 3 for coughing.</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Coughing Affected</td> <td>0/16 or 0%</td> <td>4/16 or 25%</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Abnormal Respiration Affected</td> <td>3/16 or 19%</td> <td>12/16 or 75%</td> </tr> </tbody> </table>	Treatment Group	Vaccinates	Controls	Hyperthermia Affected	15/16 or 94%	16/16 or 100%	Treatment Group		Vaccinates	Controls	Nasal Discharge	Mildly Affected	5/16 or 31%	1/16 or 6%	Moderately Affected	7/16 or 44%	2/16 or 13%	Severely Affected	4/16 or 25%	13/16 or 80%	Treatment Group	Vaccinates	Controls	Coughing Affected	0/16 or 0%	4/16 or 25%	Treatment Group	Vaccinates	Controls	Abnormal Respiration Affected	3/16 or 19%	12/16 or 75%
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	<p>Animals were considered positive for Virus Isolation (VI) with recovery of at least one positive nasal swab.</p> <table border="1" data-bbox="464 465 1453 546"> <thead> <tr> <th data-bbox="464 465 892 506">Treatment Group</th> <th data-bbox="892 465 1171 506">Vaccinates</th> <th data-bbox="1171 465 1453 506">Controls</th> </tr> </thead> <tbody> <tr> <td data-bbox="464 506 892 546">Virus Isolation Recovery</td> <td data-bbox="892 506 1171 546">6/16 or 37%</td> <td data-bbox="1171 506 1453 546">12/16 or 75%</td> </tr> </tbody> </table> <table border="1" data-bbox="464 645 1453 797"> <thead> <tr> <th data-bbox="464 645 738 685">Treatment Group</th> <th data-bbox="738 645 956 685"></th> <th data-bbox="956 645 1235 685">Vaccinates</th> <th data-bbox="1235 645 1453 685">Controls</th> </tr> </thead> <tbody> <tr> <td data-bbox="464 685 738 725" rowspan="3">Virus Isolation, Duration</td> <td data-bbox="738 685 956 725">0 Days</td> <td data-bbox="956 685 1235 725">10/16 or 63%</td> <td data-bbox="1235 685 1453 725">4/16 or 25%</td> </tr> <tr> <td data-bbox="738 725 956 766">1 Day</td> <td data-bbox="956 725 1235 766">5/16 or 31%</td> <td data-bbox="1235 725 1453 766">6/16 or 38%</td> </tr> <tr> <td data-bbox="738 766 956 797">≥ 2 Days</td> <td data-bbox="956 766 1235 797">1/16 or 6%</td> <td data-bbox="1235 766 1453 797">6/16 or 38%</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Treatment Group	Vaccinates	Controls	Virus Isolation Recovery	6/16 or 37%	12/16 or 75%	Treatment Group		Vaccinates	Controls	Virus Isolation, Duration	0 Days	10/16 or 63%	4/16 or 25%	1 Day	5/16 or 31%	6/16 or 38%	≥ 2 Days	1/16 or 6%	6/16 or 38%
Treatment Group	Vaccinates	Controls																			
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	1 Day	5/16 or 31%	6/16 or 38%																		
	≥ 2 Days	1/16 or 6%	6/16 or 38%																		
USDA Approval Date	September 26, 2006																				

Table 2. Rectal body temperatures of horses on days -1 to 14 post-challenge with virulent EHV-1

Horse No	Group	Rectal body temperatures on days post-challenge with EHV-1:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
280		102.3	101.3	102.3	102.4	102.1	102.5	103.0	104.0	102.5	101.0	100.2	100.2	100.2	100.6	100.8	101.1
282		101.6	101.9	100.6	103.1	103.2	103.2	102.1	102.4	102.1	103.3	100.0	99.4	99.0	100.2	100.2	99.8
284		101.5	101.3	100.0	102.8	103.8	101.9	101.4	102.1	101.4	101.2	100.0	99.5	98.9	100.5	99.9	99.7
287		101.5	101.2	99.2	102.2	102.2	102.2	102.7	102.3	100.8	100.7	99.9	99.3	99.9	100.2	98.9	99.8
291		100.7	101.2	102.0	103.5	103.7	103.6	102.0	102.4	102.3	101.6	100.1	99.9	99.5	100.8	100.1	99.3
294		100.8	101.6	100.2	102.4	101.4	101.9	102.5	101.1	99.9	100.1	100.0	99.1	99.0	100.2	100.1	100.1
295		101.3	101.1	100.8	102.9	101.6	102.0	102.1	102.1	101.1	100.9	100.5	99.9	98.9	100.2	100.0	100.0
296		102.0	102.4	100.0	103.1	102.4	101.9	102.9	102.4	101.9	101.0	100.7	99.3	98.1	101.1	100.1	99.4
297		101.8	102.1	100.8	101.9	101.0	100.3	100.9	102.6	101.5	100.7	100.5	100.2	99.9	100.1	100.8	100.2
298		101.0	103.6	102.4	105.5	103.6	102.1	102.8	102.1	103.1	100.2	100.5	99.2	100.9	101	100.2	99.5
299		102.5	101.8	101.5	102.4	102.0	104.0	101.0	104.3	103.5	105.4	100.3	100.0	99.5	100.7	100.0	99.7
305		100.9	102.7	100.2	103.1	101.6	101.9	102.9	105.0	105.8	100.2	100.5	99.9	99.5	100.8	100.0	100.0
307		102.5	103.0	102.5	102.4	101.9	102.6	103.4	102.3	101.4	101.3	101.2	100.4	101.0	101.7	100.2	100.8
308		101.5	101.2	101.7	101.9	102.1	102.2	102.9	101.4	102.4	100.3	100.2	99.1	99.7	101.6	100.3	100.0
313		102.0	103.2	101.8	104.0	102.2	102.4	103.1	104.0	102.9	101.0	100.0	100.1	100.0	100.5	100.1	100.3
315		103.0	102.1	100.6	104.0	103.3	104.3	101.7	104.0	102.7	102.5	101.1	99.7	98.6	99.7	99.5	99.8
285		101.4	101.0	102.3	105.1	103.5	102.5	101.4	100.6	100.1	100.0	100.9	100.2	99.7	99.9	100.8	100.1
286		101.4	101.0	101.1	106.8	104.1	103.4	100.2	101.7	100.3	100.7	100.0	100.0	99.2	101.2	100.1	101.1
288		101.5	101.0	101.0	106.9	102.6	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		101.2	102.3	101.3	105.3	102.4	104.9	102.9	102.6	101.4	100.7	99.9	99.8	100.2	100.2	99.0	100.0
293		101.0	101.7	99.3	106.3	103.7	104.1	102.7	102.8	103.0	101.5	100.3	100.2	99.3	100.2	100.9	100.1
300		102.1	101.1	100.1	106.1	103.5	102.7	100.2	99.7	100.1	103.0	100.5	99.9	99.4	100.3	100.0	99.9
302		103.1	102.8	101.8	105.1	102.6	104.3	103.5	100.9	104.0	101.4	100.2	99.9	99.2	100.6	100.0	100.0
303		101.2	101.5	100.6	104.2	102.1	104.9	102.9	103.5	103.9	100.2	99.9	99.8	99.2	99.7	99.4	99.9
304		102.5	103.5	100.2	105.0	104.5	103.4	103.3	102.7	103.8	103.8	100.8	101.1	98.5	100.1	99.8	99.8
306		100.4	102.7	101.6	106.2	103.1	102.4	100.2	101.6	100.1	101.3	99.5	100.0	98.4	100.4	99.0	98.8
309		102.0	103.2	103.4	104.5	103.3	103.6	103.9	102.6	102.5	101.5	101.1	100.9	100.2	100.2	100.2	100.0
310		101.9	101.1	101.8	106.2	103.5	103.9	102.7	103.6	102.0	101.6	99.7	99.4	98.8	100.2	99.4	99.3
311		101.9	101.8	100.9	106.1	104.8	103.7	103.8	103.2	102.8	102.7	101.3	100.1	99.7	100.1	99.7	100.0
312		102.8	102.9	100.7	105.2	103.7	104.1	102.3	103.8	102.3	101.0	101.7	100.7	101.8	100.4	100.1	100.0
314		101.1	101.8	100.8	107.0	104.2	104.5	104.1	104.5	102.2	102.7	100.4	99.0	98.7	99.7	99.2	99.5
316		102.4	102.5	101.8	101.5	104.2	104.9	104.6	102.9	105.4	103.4	100.8	99.8	99.6	101.9	101.2	101.0

Vaccinates

Placebo
Controls

Body Temperatures $\geq 102.5^{\circ}\text{F}$ were considered to be elevated.

Table 3. Nasal discharge scores in horses on days -1 to 14 post-challenge with virulent EHV-1

Horse No	Group	Nasal Discharge Scores ^a on days post-challenge with EHV-1:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
280		0	0	0	0	2	1	1	0	0	0	2	0	1	0	0	0
282		0	0	0	0	1	1	1	1	2	1	1	2	2	0	0	0
284		0	0	0	0	0	1	0	1	1	0	1	0	2	0	0	0
287		0	0	0	0	1	0	1	1	1	0	0	0	0	0	1	0
291		0	0	0	0	1	1	1	1	2	0	1	3	1	0	0	0
294		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
295		0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
296		0	0	0	0	1	0	0	0	0	1	2	0	0	0	0	0
297		0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
298		0	0	0	1	1	1	0	0	0	1	0	0	0	0	0	0
299		0	0	0	1	1	1	1	1	1	1	0	2	2	0	0	0
305		0	0	0	0	1	2	1	1	1	1	0	0	0	0	0	0
307		0	0	0	1	1	1	2	1	2	3	2	2	1	0	0	0
308		0	0	0	0	1	1	3	1	0	1	0	1	1	0	0	0
313		0	0	0	0	1	1	1	1	2	2	2	2	1	1	0	0
315		0	0	0	0	1	1	1	1	1	2	2	3	2	0	0	0
285		0	0	0	0	2	2	1	3	1	1	0	0	0	0	0	0
286		0	0	0	1	2	3	2	3	2	0	0	0	0	0	0	0
288		0	0	0	1	1	1	1	1	1	1	0	0	0	0	0	0
290		0	0	0	0	2	2	2	2	1	1	0	0	0	0	0	0
293		0	0	0	0	1	3	3	3	3	3	2	2	2	2	0	0
300		0	0	0	0	1	1	2	3	1	0	0	0	0	0	0	0
302		0	0	0	0	2	3	2	3	3	3	1	2	2	0	0	0
303		0	0	0	0	2	1	3	2	2	2	1	2	2	1	0	0
304	Placebo Controls	1	0	1	1	2	3	3	2	2	2	3	2	2	1	0	0
306		0	0	0	0	1	2	2	1	2	1	2	0	0	0	0	0
309		0	0	0	0	2	3	3	3	3	2	2	1	2	0	0	0
310		0	0	0	0	1	3	2	3	3	3	3	3	2	2	0	0
311		0	0	0	0	1	3	2	3	3	3	2	2	1	2	2	1
312		0	0	0	0	1	3	1	2	2	3	2	0	0	0	0	0
314		0	0	0	0	1	3	2	2	2	3	3	2	2	1	0	0
316		0	0	0	0	1	0	2	2	3	3	3	2	2	0	0	0

^a (0=normal, 1=abnormal serous, 2=slight mucopurulent, 3=copious mucopurulent

Table 4. Coughing scores of horses on days -1 to 14 post-challenge with v-rulent BHV-1
Coughing Scores^a on days post-challenge with BHV-1:

Horse No	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
280	Vaccinates	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
282		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
284		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
287		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
291		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
294		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
295		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
296		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
297		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
298		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
299		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
307		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
308		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
313	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
315	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
285	Placebo Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
286		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
288		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
290		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
293		0	0	0	0	0	0	0	0	0	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
302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
303		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
304		0	0	0	0	0	0	0	2	3	3	3	3	3	2	2	2	2
305		0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0
309		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
310		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
312		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
314	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
316	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	

0=normal, 1=coughed once during observation, 2=coughed twice during observation, 3=coughed three or more times during observation

Animals were scored as a 2 or 3 for coughing

Table 5. Respiration rate scores of horses on days -1 to 14 post-challenge with virulent EHV-1
 Respiration Rate Scores^a on days post-challenge with EHV-1:

Horse No	Group	Respiration Rate Scores ^a on days post-challenge with EHV-1:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
280	Vaccinates	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
282		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
284		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
287		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
291		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
294		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
295		0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
296		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
297		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
298		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
299		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
307		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
308		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
313	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
315	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
285	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
286	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
288	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
290	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
293	0	0	0	1	1	1	0	0	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	
302	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
303	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
304	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
306	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
309	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	
310	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	
311	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	
312	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
314	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	
316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

^a0=normal, 1=Abnormal (>36 per minute, dyspnea, tachypnea)

Table 6. Isolation of virus from nasal swabs of horses on days post challenge with virulent EHV-1

Horse No	Group	Virus isolation from nasal swabs* on days post-challenge with EHV-1:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
280		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
282		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
284		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
287		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
291		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
294		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
295		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
296	Vaccinates	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
297		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
298		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
299		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
305		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
307		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
308		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
313		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
315		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
285		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
286		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
288		-	-	+	+	-	Died	-	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
293		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
300		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
302		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
303	Placebo	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
304	Controls	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	-
306		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
309		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
310		-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	-
311		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
312		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
314		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
316		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

(-)=no virus isolated, (+)=virus isolated

Study Type	Efficacy									
Pertaining to	Equine Herpesvirus-Subtype 4 (EHV-4)									
Study Purpose	Efficacy against respiratory disease caused by EHV-4									
Product Administration	Two doses, administered intramuscularly, 3 weeks apart									
Study Animals	21 vaccinates and 11 controls, seronegative to EHV-4. Horses were 6 months of age, mixed sex.									
Challenge Description	Horses were challenged with EHV-4, 21 days post second vaccination.									
Interval observed after challenge	Observed for 14 days post challenge for clinical signs of respiratory disease.									
Results	<p>Animals displaying clinical signs were considered to be affected by the challenge if they had slight or copious amounts of nasal discharge for two or more consecutive days, and exhibit coughing for two or more consecutive days.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Presence of clinical signs</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>21</td> <td>2</td> </tr> <tr> <td>Controls</td> <td>11</td> <td>8</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Group	# of Animals	Presence of clinical signs	Vaccinates	21	2	Controls	11	8
Group	# of Animals	Presence of clinical signs								
Vaccinates	21	2								
Controls	11	8								
USDA Approval Date	April 7, 2004									

Nasal Discharge

Horse No.	Group	Nasal discharge observations on days post challenge with EHV-4:																
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	Vaccinates	N	N	N	N	SM	N	N	N	SM	N	S	N	N	N	SM	N	
2		N	N	N	N	SM	N	S	N	N	SM	N	N	N	N	N	N	
3		N	N	N	N	N	SM	N	N	CM	N	SM	N	N	N	N	SM	N
4		N	N	N	N	N	N	N	SM	N	N	N	N	N	N	N	N	N
7		N	N	N	N	SM	N	N	N	N	N	N	N	N	SM	N	N	N
9		N	N	N	N	N	N	N	SM	N	N	N	CM	N	N	N	SM	N
12		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
14		N	N	N	N	SM	SM	SM	SM	SM	SM	CM	N	N	N	N	SM	N
15		N	N	N	N	SM	CM	SM	CM	SM	SM	SM	N	N	N	N	N	N
19		N	N	N	N	SM	N	N	N	N	N	N	N	N	N	N	N	N
20		N	N	N	N	N	SM	N	S	SM	N	N	N	SM	N	SM	N	N
24		N	N	N	N	N	N	N	S	N	SM	N	N	N	N	N	N	SM
27		N	N	N	N	N	SM	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	SM	N	N	SM	N	N	N	N	SM	N	N	N
33		N	N	N	N	SM	N	CM	N	N	N	N	N	N	N	N	S	SM
37		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
45		N	N	N	N	N	N	N	N	N	SM	N	N	N	N	SM	S	N
47		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
58		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
61		N	N	N	N	N	N	N	N	N	N	N	SM	N	N	N	N	SM
83	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
5	Controls	N	N	N	N	N	CM	CM	CM	CM	CM	N	CM	N	N	N	N	
25		N	N	N	N	N	CM	CM	N	CM	CM	CM	N	N	CM	N	N	
39		N	N	N	N	SM	CM	N	CM	N	N	CM	N	N	N	N	N	N
40		N	N	N	N	SM	CM	CM	CM	N	N	N	N	N	N	N	N	N
43		N	N	N	N	SM	SM	N	CM	CM	N	N	N	SM	N	N	N	N
59		N	N	N	N	N	N	CM	CM	CM	N	CM	N	N	N	N	N	SM
63		N	N	N	N	N	N	N	N	N	CM	CM	N	N	N	N	SM	CM
65		N	N	N	N	N	SM	CM	CM	CM	N	SM	N	N	N	N	N	SM
71		N	N	N	N	N	CM	SM	CM	CM	N	CM	N	N	CM	CM	N	N
79		N	N	N	N	SM	N	CM	CM	CM	SM	N	N	N	N	N	SM	N
91		N	N	N	N	N	CM	CM	CM	CM	N	N	N	N	N	N	N	N

N=normal (score of 0), S=copious serous discharge (score of 1), SM=slight mucopurulent discharge (score of 2), CM=copious mucopurulent discharge (score of 4)

Coughing

Horse No.	Group	Coughing observations on days post challenge with EHV-4:																
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	Vaccinates	N	N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	
2		N	N	N	N	N	N	N	N	C	N	N	N	N	N	N	N	C
3		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	C	N
4		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
7		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
9		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
12		N	N	N	N	N	N	N	N	N	N	N	N	C	N	N	N	N
14		N	N	N	N	N	C	C	C	N	N	C	N	N	N	N	C	N
15		N	N	N	N	N	C	C	C	C	C	C	N	C	N	C	N	N
19		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
24		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
27		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	N
33		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
37		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
45		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
47		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
58		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
61		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
83	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
5	Controls	N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	
25		N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
39		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40		N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
43		N	N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N
59		N	N	N	N	N	N	C	N	C	N	N	N	N	N	N	N	N
63		N	N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	N
65		N	N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N
71		N	N	N	N	N	N	C	C	C	N	N	N	N	N	N	N	N
79		N	N	N	N	N	N	C	N	C	C	N	N	N	N	N	N	N
91		N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N

N=no coughing, C=coughing

Study Type	Efficacy																																	
Pertaining to	Equine Herpesvirus-Subtype 4 (EHV-4)																																	
Study Purpose	Efficacy against respiratory disease and shedding caused by EHV-4																																	
Product Administration	Two doses, administered intramuscularly, 21 days apart																																	
Study Animals	16 vaccinates and 15 controls, seronegative to EHV-4. Horses were 6 months of age, mixed sex.																																	
Challenge Description	Horses were challenged with EHV-4, 21 days post second vaccination.																																	
Interval observed after challenge	Horses were observed daily for 21 days post-challenge for clinical signs. Nasal swabs were collected daily for virus isolation.																																	
Results	<p><u>Virus Shedding</u> – The number of post-challenge days between the last and first, inclusive, with a positive titer.</p> <table border="1"> <thead> <tr> <th colspan="6">Duration of Virus Shedding</th> </tr> <tr> <th>Group</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>3</td> <td>5</td> <td>6</td> <td>8</td> <td>14</td> </tr> <tr> <td>Controls</td> <td>4</td> <td>7</td> <td>11</td> <td>15</td> <td>19</td> </tr> </tbody> </table> <p><u>Nasal Discharge</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th>Unaffected</th> <th>Affected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>4 (25%)</td> <td>12 (75%)</td> </tr> <tr> <td>Controls</td> <td>0 (0%)</td> <td>15 (100%)</td> </tr> </tbody> </table> <p>Coughing was not observed in vaccinates or controls.</p> <p>Raw data shown on attached pages.</p>	Duration of Virus Shedding						Group	Minimum	Q1	Median	Q3	Maximum	Vaccinates	3	5	6	8	14	Controls	4	7	11	15	19	Group	Unaffected	Affected	Vaccinates	4 (25%)	12 (75%)	Controls	0 (0%)	15 (100%)
Duration of Virus Shedding																																		
Group	Minimum	Q1	Median	Q3	Maximum																													
Vaccinates	3	5	6	8	14																													
Controls	4	7	11	15	19																													
Group	Unaffected	Affected																																
Vaccinates	4 (25%)	12 (75%)																																
Controls	0 (0%)	15 (100%)																																
USDA Approval Date	July 2, 2007																																	

Nasal Discharge – Vaccinates

Horse No	Nasal discharge scores ^a on post-challenge days.....																						
	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
648	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
649	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
653	0	0	0	0	0	1	2	0	2	1	1	0	3	0	1	0	0	0	0	0	0	0	0
654	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
657	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
661	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
663	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
666	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
667	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
669	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
671	0	0	0	0	0	2	1	0	1	0	3	0	0	0	0	0	0	0	0	0	0	0	0
672	0	0	0	0	0	0	1	0	1	0	1	3	0	1	0	0	1	0	0	0	0	0	0
673	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
676	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
677	0	0	0	0	0	1	1	1	1	2	1	0	1	0	0	0	0	0	0	0	0	0	0
678	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Avg	0	0	0	0	0	0.5	0.5	0.13	0.44	0.19	0.5	0.19	0.31	0.06	0.06	0	0.06	0	0	0	0	0	0

^a (0=normal, 1=abnormal serous, 2=slight mucopurulent, 3=copius mucopurulent)

Nasal Discharge – Controls

Horse No	Nasal discharge scores ^a (Day Post-Challenge)																						
	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
650	0	0	0	0	0	0	1	1	2	2	0	1	1	1	1	1	1	1	1	0	0	0	0
651	0	0	0	0	0	1	0	1	1	1	1	1	0	1	1	1	0	1	0	0	0	0	0
652	0	0	0	0	0	0	2	1	2	2	3	3	1	2	1	1	1	0	0	0	0	0	0
655	0	0	0	0	0	2	2	1	2	2	3	2	1	0	2	1	0	0	0	0	0	0	0
656	0	0	0	0	0	1	1	1	1	2	3	1	1	1	3	1	1	1	1	1	0	0	0
658	0	0	0	0	0	2	0	1	1	0	0	1	1	0	0	1	0	0	0	0	1	0	0
659	0	0	0	0	0	1	1	2	2	1	0	3	0	1	1	1	1	1	0	0	0	0	0
660	0	0	0	0	0	1	1	1	0	1	1	1	1	1	1	1	1	0	0	0	0	0	0
662	0	0	0	0	0	1	1	1	0	3	1	2	1	1	1	0	0	0	0	0	0	0	0
664	0	0	0	0	0	0	1	1	1	0	0	1	0	1	1	1	0	0	1	0	0	0	0
665	0	0	0	0	0	1	1	3	1	3	3	3	1	1	2	1	0	0	1	0	0	0	0
668	0	0	0	0	0	0	1	1	2	1	1	3	3	1	1	2	1	1	0	1	1	0	0
670	0	0	0	0	0	1	1	1	2	2	1	2	1	1	0	1	1	1	1	0	0	0	0
674	0	0	0	0	0	1	1	2	2	3	1	0	0	1	0	1	0	0	0	0	0	0	0
675	0	0	0	0	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	0	0	0	0
Avg	0	0	0	0	0	0.87	1	1.27	1.27	1.6	1.27	1.6	0.87	0.93	1.07	1	1.36	1.35	1.35	1.24	1.18	1.18	1.24

^a (0=normal, 1=abnormal serous, 2=slight mucopurulent, 3=copius mucopurulent)

Virus Isolation – Vaccinates

Horse No	Group	Day Post-Challenge Viral Titers (Log ₁₀ TCID ₅₀ /mL)																					
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
648	Vaccinate	0	0	0	0	3.53	<1	3.19	4.53	2.53	0	<1	0	0	0	0	0	0	0	0	0	0	0
649	Vaccinate	0	0	0	0	2.53	2.86	3.53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
653	Vaccinate	0	0	0	<1	3.53	3.53	3.32	4.07	0	0	0	0	0	0	1.86	<1	0	0	0	0	0	0
654	Vaccinate	0	0	0	0	2.07	4.07	3.32	3.19	0	0	0	0	0	0	0	0	0	0	0	0	0	0
657	Vaccinate	0	0	<1	3.19	3.07	3.92	3.19	3.53	2.19	2.07	0	0	0	0	0	0	0	0	0	0	0	0
661	Vaccinate	0	0	0	0	2.86	4.19	4.19	3.86	2.19	<1	0	0	0	0	0	0	0	0	0	0	0	0
663	Vaccinate	0	0	0	2.19	2.19	2.19	2.53	2.53	0	0	0	0	0	0	0	0	0	0	0	0	0	0
666	Vaccinate	0	0	0	0	3.19	3.07	4.07	2.19	1.86	0	0	0	0	0	0	0	0	0	0	0	0	0
667	Vaccinate	0	0	0	0	2.86	2.53	4.53	4.86	1.86	0	0	0	0	0	0	0	0	0	0	0	0	0
669	Vaccinate	0	0	0	0	2.52	1.86	3.19	3.53	2.32	0	0	0	0	0	0	0	0	0	0	0	0	0
671	Vaccinate	0	0	0	0	3.38	1.86	4.19	3.53	2.53	1.86	2.86	<1	<1	0	0	0	0	0	0	0	0	0
672	Vaccinate	0	0	0	0	<1	2.01	2.32	2.19	1.86	<1	0	0	0	0	0	0	0	0	0	0	0	0
673	Vaccinate	0	0	0	2.32	<1	3.07	3.19	2.86	0	0	1.86	1.86	2.19	0	0	0	0	0	0	0	0	0
676	Vaccinate	0	0	0	0	0	0	2.32	<1	2.86	2.32	<1	0	0	0	0	0	0	0	0	0	0	0
677	Vaccinate	0	0	0	<1	4.53	3.53	2.86	3.19	2.86	<1	<1	0	0	0	0	0	0	0	0	0	0	0
678	Vaccinate	0	0	0	1.86	<1	<1	0	1.86	2.32	0	0	0	0	0	0	0	0	0	0	0	0	0
	Avg	0	0	0.03	0.66	2.36	2.48	2.98	3.02	1.44	0.52	0.51	0.18	0.17	0	0	0.12	0.03	0	0	0	0	0

Virus Isolation – Controls

Horse No	Group	Day Post-Challenge Viral Titers (Log ₁₀ TCID ₅₀ /mL)																					
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
650	Control	0	0	0	0	<1	2.19	4.5	4.07	0	0	0	0	0	0	0	0	0	0	0	0	0	0
651	Control	0	0	0	2.32	2.07	3.32	4.19	4.86	4.32	3.19	2.01	2.19	0	0	<1	0	0	0	0	0	0	0
652	Control	0	0	0	1.86	2.53	4.19	3.53	4.32	3.86	4.32	4.32	3.19	2.19	0	<1	1.86	<1	2.19	2.07	<1	0	0
655	Control	0	0	0	0	<1	3.53	5.07	4.86	3.07	2.53	0	0	0	0	0	<1	0	1.86	2.07	<1	0	0
656	Control	0	0	0	0	3.53	3.07	4.32	4.53	3.07	2.69	<1	0	0	0	<1	0	0	0	0	0	0	<1
658	Control	0	0	0	1.86	3.19	4.19	5.52	4.32	3.19	<1	0	0	0	0	0	0	0	0	0	0	0	0
659	Control	0	0	0	0	<1	3.07	3.07	2.07	1.86	<1	0	0	<1	0	0	<1	0	0	0	0	0	0
660	Control	0	0	0	<1	3.07	3.86	4.19	3.86	2.86	2.86	2.19	0	0	0	0	0	<1	0	0	0	0	0
662	Control	0	0	0	2.19	4.53	3.53	4.19	4.07	3.53	2.32	0	0	0	0	0	0	0	0	0	0	0	0
664	Control	0	0	0	0	3.19	4.19	5.19	4.01	3.19	1.86	1.86	0	0	0	0	0	0	0	0	0	0	0
665	Control	0	0	<1	0	3.19	4.19	4.32	3.86	3.19	2.86	2.53	2.07	0	0	0	0	0	0	0	0	0	0
668	Control	0	0	0	0	3.53	4.19	4.07	4.19	4.32	2.53	<1	0	0	0	0	0	0	0	0	0	0	0
670	Control	0	0	0	0	3.86	3.53	3.53	3.19	2.53	2.07	1.86	<1	<1	2.07	2.32	0	0	0	0	0	0	0
674	Control	0	0	0	<1	3.07	3.86	3.53	2.86	2.53	2.32	0	0	3.86	3.19	1.86	2.07	0	1.86	0	0	0	0
675	Control	0	0	0	2.32	3.86	2.52	4.32	5.32	4.07	3.01	<1	<1	0	0	0	0	0	0	0	0	0	0
	Avg	0	0	0.03	0.77	2.74	3.56	4.24	4.03	3.04	2.24	1.09	0.56	<0.50	0.35	0.36	0.33	0.07	0.39	0.28	0.07	0	0.03

Study Type	Efficacy
Pertaining to	Equine Influenza Virus (EIV)
Study Purpose	To demonstrate efficacy of updated EIV strains FL/13 and RI/07
Product Administration	
Study Animals	
Challenge Description	
Interval observed after 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	March 8, 2016

Study Type	Efficacy																		
Pertaining to	Equine Influenza Virus (EIV)																		
Study Purpose	To demonstrate efficacy against EIV six months after vaccination.																		
Product Administration	Two doses administered intramuscularly (IM) three weeks apart.																		
Study Animals	18 vaccinate and 7 control horses were used at 6 months of age.																		
Challenge Description	All horses were challenged with EIV strain A/equine/Kentucky/99 six months post second vaccination.																		
Interval observed after challenge	Horses were observed daily for 14 days post-challenge for clinical signs. Nasal swabs were collected daily for virus isolation.																		
Results	<p>Disease Prevalence – presence/absence of any clinical sign at any occasion during the observation period (nasal discharge, coughing, respiration, temperature >102.5°F).</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Presence of clinical signs</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>18</td> <td>14</td> </tr> <tr> <td>Controls</td> <td>7</td> <td>7</td> </tr> </tbody> </table> <p>Virus shedding prevalence – a horse was considered negative for shedding if all 14 daily post-challenge swabs were virus negative, otherwise it was positive.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Virus Isolation</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>18</td> <td>12</td> </tr> <tr> <td>Controls</td> <td>7</td> <td>7</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Group	# of Animals	Presence of clinical signs	Vaccinates	18	14	Controls	7	7	Group	# of Animals	Virus Isolation	Vaccinates	18	12	Controls	7	7
Group	# of Animals	Presence of clinical signs																	
Vaccinates	18	14																	
Controls	7	7																	
Group	# of Animals	Virus Isolation																	
Vaccinates	18	12																	
Controls	7	7																	
USDA Approval Date	August 8, 2005																		

Table 1. Rectal body temperatures of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99.

Horse No.	Group	Body temperatures (°F) on days post challenge with EIV KY99:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	Vaccinates	100.3	100.0	99.6	99.9	101.5	101.1	100.0	99.8	100.2	99.1	100.2	98.1	100.7	99.9	100.1	100.6
2		99.2	100.0	99.7	99.0	99.5	99.8	98.9	99.3	100.0	99.1	99.8	99.2	100.8	99.6	100.3	100.1
4		98.8	99.1	99.9	100.1	98.6	99.8	98.9	99.3	98.9	97.8	99.2	99.2	100.5	99.9	101.7	100.0
14		99.8	100.9	100.6	101.9	99.8	99.8	99.9	100.0	99.2	99.1	100.3	99.2	100.8	99.9	100.2	99.7
16		99.1	100.1	99.3	102.8	100.5	101.5	100.1	98.9	98.8	98.5	98.3	98.8	100.1	99.4	100.0	100.6
19		99.7	100.6	99.9	100.0	99.6	100.2	99.4	100.0	99.7	99.5	100.0	98.6	100.0	100.6	100.9	100.2
29		100.3	100.5	99.6	99.7	99.7	100.0	99.3	99.2	99.2	100.5	99.8	100.0	100.5	100.9	100.2	100.3
30		101.2	100.1	100.5	105.4	102.6	104.4	102.1	100.9	99.6	100.4	101.5	100.7	102.4	101.3	102.1	101.4
32		98.8	100.8	100.0	100.4	99.3	100.5	99.6	99.7	99.7	98.3	99.6	100.0	101.2	100.0	100.4	102.7
33		99.2	100.0	99.4	104.6	100.0	100.0	98.7	100.0	100.8	98.6	99.0	99.3	100.6	99.6	100.9	100.6
34		99.8	100.2	99.7	103.6	100.0	101.3	102.1	102.7	102.1	101.5	102.9	102.0	100.4	100.1	99.8	99.4
35		99.2	99.7	99.1	99.5	99.5	100.6	100.4	99.7	98.8	98.5	100.1	100.1	101.6	100.2	100.3	100.5
36		99.7	99.6	99.8	100.5	100.0	100.5	99.6	99.4	100.4	98.6	99.2	99.0	100.6	100.7	99.9	100.4
39		99.7	100.4	100.0	100.5	100.3	100.5	98.8	100.0	99.4	98.7	100.8	99.6	100.5	100.1	100.9	100.0
40		99.4	100.4	99.9	102.2	99.9	101.6	100.1	100.1	99.1	99.1	99.7	99.5	100.3	99.2	99.9	100.4
41		99.2	100.0	99.4	102.6	99.7	99.7	99.4	99.6	99.7	99.3	99.6	98.8	100.2	99.0	100.1	100.2
43	99.7	100.4	99.8	99.4	99.8	100.1	98.6	98.8	98.7	99.0	99.4	99.6	99.6	99.9	99.6	99.9	
47	100.2	100.2	100.1	101.6	99.2	100.1	99.9	100.5	99.6	99.3	98.8	99.5	99.3	99.7	99.5	100.6	
3	Controls	99.5	100.2	99.6	104.5	103.1	103.8	103.7	103.6	102.6	102.4	104.7	102.7	102.4	101.8	102.0	100.9
8		99.0	99.9	98.8	101.9	100.8	103.0	99.1	100.7	100.2	98.9	99.9	99.3	100.4	100.1	100.3	99.6
11		100.4	100.5	100.1	101.9	99.9	99.8	100.9	100.1	99.2	100.6	101.3	99.2	101.0	99.9	100.6	100.3
13		99.5	99.7	100.3	103.6	102.4	102.8	99.5	99.3	100.4	99.5	99.2	98.8	101.0	100.1	100.7	99.8
25		100.1	100.6	99.5	104.7	103.6	102.2	103.1	104.2	103.2	102.3	105.4	99.5	99.8	99.8	99.7	100.1
38		99.2	100.0	99.0	104.7	103.7	104.0	104.6	104.7	103.0	103.6	103.3	101.6	101.2	99.5	99.2	99.5
44		99.1	99.9	99.8	103.2	102.6	104.4	97.2	99.8	100.4	104.6	103.8	102.6	102.9	100.6	100.0	99.4

Table 2. Coughing observations of horses vaccinated with vaccinated 111103 on days post-challenge with virulent EIV KY99.

Horse No	Group	Coughing observations on days post-challenge with EIV KY99:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1		N	N	N	N	C	C	C,C	C	C	N	N	N	N	N	N	N
2		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4		N	N	N	N	N	N	N	N	N	N	N	N	C	N	N	N
14		N	N	N	N	N	N	C	N	N	C	C	C	N	N	N	N
16		N	N	N	C,C	C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	N	N	N	N
19		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	N	N	N	C	N	N	N	N	N	N	N
30		N	N	N	C,C	C	C,C	C,C	C,C	C,C	C,C	N	N	N	N	N	N
32		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33	Vaccinates	N	N	N	C,C	C	C	C	N	N	C,C	C	C	N	N	N	N
34		N	N	N	N	N	N	C,C	C,C	C,C	C,C	C	C	N	N	N	N
35		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
36		N	N	N	C	N	N	N	N	N	N	N	N	N	N	N	N
39		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
41		N	N	N	N	N	N	C	C	C	N	N	C	N	N	N	N
43		N	N	N	N	N	N	N	N	N	C	C,C	N	N	N	N	N
47		N	N	N	N	N	N	N	N	N	N	C	N	N	N	N	N
3		N	N	N	C,C	C,C	C,C	C,C	C	C	C,C	C,C	C,C	N	N	N	N
8		N	N	N	C,C	C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	N	N	N	N
11		N	N	N	N	N	N	N	N	C	C	C	C	N	N	N	N
13		N	N	C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	C	C	N	N	N	N
25		N	N	N	C,C	C	C,C	C,C	C,C	N	N	C,C	C,C	N	N	N	N
38		N	N	N	C,C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	N	N	N	N
44		N	N	N	C,C	C	C	C,C	N	N	C	N	C	C,C	N	N	N

N=no coughing, C=coughing 1 time during the observation period, C,C=coughing 2 or more times during the observation period

Table 3. Nasal discharge observations of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99.

Horse No.	Group	Nasal discharge observations on days post-challenge with EIV KY99:																
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	Vaccinates	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
2		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
14		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
16		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
19		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
30		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
32		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
34		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
35		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
36		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
39		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
41	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
43	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
47	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
3	Controls	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
8		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
11		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
13		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
25		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
38		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
44		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N=normal (score of 0), S=copious serous discharge (score of 1), SM=slight mucopurulent discharge (score of 2), CM=copious mucopurulent discharge (score of 4)

Table 4. Abnormal respiration and depression observations of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99.

Horse No	Group	Observations on days post-challenge with EIV KY99:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
14		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
16		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
19		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
30		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
32		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33	Vaccinates	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
34		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
35		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
36		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
39		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
41		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
43		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
47		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
3		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
8		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
11		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
13		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
25	Controls	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
38		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
44		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N=normal, Ab=abnormal respiration of >36 per minute, D=depression, lethargy or inappetence. Observations were scored as not observed (score of 0) and observed (score of 1)

Table 5. Virus isolation from nasal swabs from horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99.

Horse No	Group	Isolation of virus on days post-challenge with EIV KY99:															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1		-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-
2		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14		-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
16		-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
19		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30		-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
32		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	Vaccinates	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
34		-	-	+	+	+	-	+	+	-	-	-	-	-	-	-	-
35		-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-
36		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39		-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-
40		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
41		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
43		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
47		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
8		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
11		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
13		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
25	Controls	-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
38		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
44		-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-

(-) = no virus isolated from the nasal swab, (+) = virus recovered from the nasal swab

Study Type	Safety																					
Pertaining to	ALL																					
Study Purpose	To demonstrate safety under field conditions																					
Product Administration	298 horses received 2 doses intramuscularly 3 to 4 weeks apart for primary immunization. 254 horses received 1 dose intramuscularly.																					
Study Animals	552 horses of various ages, breeds and sex in 5 different states. 177 horses were 4-months of age or younger at the time of the initial vaccination.																					
Challenge Description	Not applicable																					
Interval observed after challenge	Horses were observed immediately following vaccination and then daily for 3 days post-vaccination																					
Results	<p>Doses are reported due to difference in vaccination schedule.</p> <table border="1"> <thead> <tr> <th>Score</th> <th># of Cases</th> <th>% of Total</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>820</td> <td>96.47</td> </tr> <tr> <td>1</td> <td>25</td> <td>2.94</td> </tr> <tr> <td>2</td> <td>3</td> <td>0.35</td> </tr> <tr> <td>3</td> <td>2</td> <td>0.24</td> </tr> <tr> <td>4</td> <td>0</td> <td>0</td> </tr> <tr> <td>5</td> <td>0</td> <td>0</td> </tr> </tbody> </table> <p>Total # of Doses administered = 850</p> <p>Score Overview: 0 – No reaction 1 – Localized swelling at or near the injection site, which is not visible; detectable only by palpation. Not clinically significant. 2 – Localized visible swelling at or near the injection site. Not painful. 3 – Localized visible swelling at or near the injection site. Raised, circumscribed and painful. 4 – Visible diffused swelling involving a substantial area around the injection site. Very painful and hot. Horse is stiff and/or reluctant to move. 5 – Generalized or systemic reaction, including anaphylaxis or elevated temperature.</p>	Score	# of Cases	% of Total	0	820	96.47	1	25	2.94	2	3	0.35	3	2	0.24	4	0	0	5	0	0
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0	820	96.47																				
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USDA Approval Date	February 8, 2006																					