Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	4847.32
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prestige 5 + VEE - 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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Clostridum tetani</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against C. tetani</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously.</td></tr>
<tr><td>Study Animals</td><td>Ten guinea pigs (5 females and 5 males, 450-550g)</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Six weeks after vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of C. tetani was demonstrated in laboratory animals according to 9CFR 113.114(c).

Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool.

<table><tr><th>Pooled Guinea Pig Antitoxin titer (A.U./mL)</th></tr><tr><td>2.082</td></tr></table></td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Eastern Equine Encephalomyelitis (EEE)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against EEE</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>14 days post 2nd vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of EEE was demonstrated in laboratory animals according to 9CFR 113.207(b).

Satisfactory test result is a Virus Neutralization Titer of ≥ 1:40 in at least 9 out of 10 vaccinates (2nd stage - at least 17 out of 20 vaccinates).

<table>
<tr><th>Treatment group</th><th>Results</th><th>Test Disposition</th></tr>
<tr><td>Vaccinates</td><td>17/20 ≥ 1:40</td><td rowspan="2">Satisfactory</td></tr>
<tr><td>Controls</td><td>2/2 <1:4</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Venezuelan Equine Encephalomyelitis (VEE)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against VEE</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>14 days post 2nd vaccination, guinea pigs were bled for serological testing per SAM 110.</td></tr>
<tr><td>Results</td><td>Efficacy of VEE was demonstrated in laboratory animals according to 9CFR 113.207(b).

Satisfactory test result is a Virus Neutralization Titer of ≥ 1:4 in at least 9 of the vaccinates.

<table>
<tr><th>Treatment group</th><th>Results</th><th>Test Disposition</th></tr>
<tr><td>Vaccinates</td><td>10/10 ≥ 1:4</td><td rowspan="2">Satisfactory</td></tr>
<tr><td>Controls</td><td>2/2 <1:4</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Western Equine Encephalomyelitis (WEE)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against WEE</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>14 days post 2nd vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of WEE was demonstrated in laboratory animals according to 9CFR 113.207(b).

Satisfactory test result is a Virus Neutralization Titer of ≥ 1:40 in at least 9 of the vaccinates.

<table>
<tr><th>Treatment group</th><th>Results</th><th>Test Disposition</th></tr>
<tr><td>Vaccinates</td><td>9/10 ≥ 1:40</td><td rowspan="2">Satisfactory</td></tr>
<tr><td>Controls</td><td>2/2 <1:4</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Equine Herpesvirus-Subtype 1 (EHV-1), DA35 strain</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease caused by EHV-1</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered intramuscularly, 21 days apart.</td></tr>
<tr><td>Study Animals</td><td>16 vaccinates and 16 placebo-vaccinated controls, seronegative to EHV-1. Horses were 11 months of age, mixed sex.</td></tr>
<tr><td>Challenge Description</td><td>Horses were challenged with EHV-1, 23 days post second vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed for 14 days post challenge for clinical signs of respiratory disease.</td></tr>
<tr><td>Results</td><td>Animals displaying clinical signs were considered to be affected by the challenge. Result summaries below.

Body Temperatures ≥ 102.5°F were considered to be elevated.

<table>
<tr><th>Treatment Group</th><th>Vaccinates</th><th>Controls</th></tr>
<tr><td>Hyperthermia Affected</td><td>15/16 or 94%</td><td>16/16 or 100%</td></tr>
</table>

Observations of nasal discharged were scored as:
0 - Normal
1 - Very Mild
2 - Moderate
3 - Severe
<table>
<tr><th>Treatment Group</th><th></th><th>Vaccinates</th><th>Controls</th></tr>
<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>
</table>

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.
<table>
<tr><th>Treatment Group</th><th>Vaccinates</th><th>Controls</th></tr>
<tr><td>Coughing Affected</td><td>0/16 or 0%</td><td>4/16 or 25%</td></tr>
</table>

<table>
<tr><th>Treatment Group</th><th>Vaccinates</th><th>Controls</th></tr>
<tr><td>Abnormal Respiration Affected</td><td>3/16 or 19%</td><td>12/16 or 75%</td></tr>
</table>
</td></tr>
</table>

Animals were considered postive for Virus Isolation (VI) with recovery of at least one positive nasal swab.

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%

Raw data shown on attached pages.

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	Vaccinates	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	102.4	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	96.9	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	Placebo Controls	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

Body Temperatures ≥ 102.5°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	Vaccinates	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	1	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	2	2	2	3	2	2	0	0
285	Placebo Controls	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	Died	Diec	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		0	0	0	0	2	2	2	2	1	1	0	0	0	0	0	0
293		0	0	0	1	3	3	3	3	3	3	2	2	2	2	0	0
300		0	0	0	1	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		1	0	1	1	2	3	3	2	2	2	2	3	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	2	3	3	3	3	3	2	2	1	2	0	0	0
310		0	0	0	1	3	2	3	3	3	3	3	3	2	2	2	0
311		0	0	0	1	3	2	3	2	3	3	2	2	1	2	2	1
312		0	0	0	1	3	1	2	2	3	2	0	0	0	0	0	0
314		0	0	0	1	3	2	2	2	3	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=copius mucopurulent

Table 4. Coughing scores of horses on days -1 to 14 post-challenge with virulent EHV-1

Horse No	Group	Coughing 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	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
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	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
285	Placebo Controls	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
288		0	0	0	0	0	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		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
300		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
303		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
304		0	0	0	0	0	0	2	3	3	3	3	3	2	2	2	2
306		0	0	0	3	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
310		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
312		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
316		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

Horse No	Group	Respiration Rate Scores* 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	Placebo Controls	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	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
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	1	0	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	0	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	0	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

0=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	Vaccinates	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
282		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
284		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
287		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
291		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
294		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
295		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
296		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
297		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
298		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
299		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
305		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
307		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
308		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
313		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
315		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
285	Placebo Controls	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
286		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
288		-	-	+	+	-	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
293		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
300		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
302		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
303		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
304		-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	-
306		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
309		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
310		-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
311		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
312		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
314		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
316		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Equine Herpesvirus-Subtype 4 (EHV-4)</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease caused by EHV-4</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered intramuscularly, 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>21 vaccinates and 11 controls, seronegative to EHV-4. Horses were 6 months of age, mixed sex.</td></tr>
<tr><td>Challenge Description</td><td>Horses were challenged with EHV-4, 21 days post second vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed for 14 days post challenge for clinical signs of respiratory disease.</td></tr>
<tr><td>Results</td><td>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.

<table>
<tr><th>Group</th><th># of Animals</th><th>Presence of clinical signs</th></tr>
<tr><td>Vaccinates</td><td>21</td><td>2</td></tr>
<tr><td>Controls</td><td>11</td><td>8</td></tr>
</table>

Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>April 7, 2004</td></tr>
</table>

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	SM	N
4		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
9		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
14		N	N	N	N	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
19		N	N	N	N	SM	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
24		N	N	N	N	N	N	N	S	N	SM	N	N	N	N	N	SM
27		N	N	N	N	N	SM	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
33		N	N	N	N	SM	N	CM	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
45		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
58		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	SM	N	N	N	N	SM
83		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
40		N	N	N	N	SM	CM	CM	CM	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
59		N	N	N	N	N	N	CM	CM	CM	N	CM	N	N	N	N	SM
63		N	N	N	N	N	N	N	N	N	CM	CM	N	N	N	SM	CM
65		N	N	N	N	N	SM	CM	CM	CM	N	SM	N	N	N	N	SM
71		N	N	N	N	N	CM	SM	CM	N	N	CM	N	CM	CM	N	N
79		N	N	N	N	SM	N	CM	CM	CM	SM	N	N	N	N	SM	N
91		N	N	N	N	N	CM	CM	CM	CM	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	C	N	N	N	N	N	N	N	N	N	N
2		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	C	N
4		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
9		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	C	N	N	N	N	N
14		N	N	N	N	C	C	C	N	N	C	N	N	N	N	C	N
15		N	N	N	N	C	C	C	C	C	C	C	N	C	N	C	N
19		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
24		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
29		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
37		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
47		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
61		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
5	Controls	N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N
25		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
40		N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
43		N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N
59		N	N	N	N	N	C	N	C	N	N	N	N	N	N	N	N
63		N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	N
65		N	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N
71		N	N	N	N	N	C	C	C	N	N	N	N	N	N	N	N
79		N	N	N	N	N	C	N	C	C	N	N	N	N	N	N	N
91		N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N

N=no coughing , C=coughing

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Equine Herpesvirus-Subtype 4 (EHV-4)</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease and shedding caused by EHV-4</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered intramuscularly, 21 days apart</td></tr>
<tr><td>Study Animals</td><td>16 vaccinates and 15 controls, seronegative to EHV-4. Horses were 6 months of age, mixed sex.</td></tr>
<tr><td>Challenge Description</td><td>Horses were challenged with EHV-4, 21 days post second vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed daily for 21 days post-challenge for clinical signs. Nasal swabs were collected daily for virus isolation.</td></tr>
<tr><td>Results</td><td>Virus Shedding – The number of post-challenge days between the last and first, inclusive, with a positive titer.

<table>
<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>
<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>
</table>

Nasal Discharge

<table>
<tr><th>Group</th><th>Unaffected</th><th>Affected</th></tr>
<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>
</table>

Coughing was not observed in vaccinates or controls.

Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>July 2, 2007</td></tr>
</table>

Nasal Discharge – Vaccinates

	Nasal discharge scores[a] on post-challenge days……..																						
Horse No	-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

	Nasal discharge scores[a] (Day Post-Challenge)																						
Horse No	-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	1	0	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

		Day Post-Challenge Viral Titers (Log_{10} $TCID_{50}$/mL)																					
Horse No	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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	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	0
653	Vaccinate	0	0	0	<1	3.53	3.53	3.32	4.07	0	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	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	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	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	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	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	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	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	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	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	0
676	Vaccinate	0	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	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	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	0

Virus Isolation – Controls

		Day Post-Challenge Viral Titers (Log_{10} $TCID_{50}$/mL)																						
Horse No	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	0.38	0.33	0.07	0.39	0.28	0.07	0	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

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Equine Influenza Virus (EIV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against EIV six months after vaccination.</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly (IM) three weeks apart.</td></tr>
<tr><td>Study Animals</td><td>18 vaccinate and 7 control horses were used at 6 months of age.</td></tr>
<tr><td>Challenge Description</td><td>All horses were challenged with EIV strain A/equine/Kentucky/99 six months post second vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed daily for 14 days post-challenge for clinical signs. Nasal swabs were collected daily for virus isolation.</td></tr>
<tr><td>Results</td><td>Disease Prevalence – presence/absence of any clinical sign at any occasion during the observation period (nasal discharge, coughing, respiration, temperature >102.5°F).

<table>
<tr><th>Group</th><th># of Animals</th><th>Presence of clinical signs</th></tr>
<tr><td>Vaccinates</td><td>18</td><td>14</td></tr>
<tr><td>Controls</td><td>7</td><td>7</td></tr>
</table>

Virus shedding prevalence – a horse was considered negative for shedding if all 14 daily post-challenge swabs were virus negative, otherwise it was positive.

<table>
<tr><th>Group</th><th># of Animals</th><th>Virus Isolation</th></tr>
<tr><td>Vaccinates</td><td>18</td><td>12</td></tr>
<tr><td>Controls</td><td>7</td><td>7</td></tr>
</table>

Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>August 8, 2005</td></tr>
</table>

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	99.8	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	Vaccinates	N	N	N	N	N	C	C	C,C	C	C	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	C	N	N	N
14		N	N	N	N	N	N	N	C	N	N	C	C	N	N	N	N
16		N	N	N	N	C,C	C	C,C	C,C	C,C	N	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	N	C	N	N	N	N	N	N
30		N	N	N	N	C,C	C	C,C	C,C	C,C	N	C,C	N	N	N	N	N
32		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33		N	N	N	N	C,C	C	C	N	N	N	C,C	C	N	N	N	N
34		N	N	N	N	N	N	C,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	C	N	N	N	N	N
36		N	N	N	N	C	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	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	Controls	N	N	N	N	C,C	C,C	C,C	C,C	C	C	C,C	C,C	N	N	N	N
8		N	N	N	N	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,C	C	N	N	N	N
13		N	N	N	C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	C	N	N	N	N
25		N	N	N	N	C,C	C	C,C	C,C	C,C	N	N	C,C	N	N	N	N
38		N	N	N	N	C,C	C,C	C,C	C,C	C,C	C,C	C,C	C,C	N	N	N	N
44		N	N	N	N	C,C	C	C	C,C	N	N	C	N	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	CM	N	N	CM	N	N	N	SM	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	SM	CM	SM	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	SM	N	SM	N	N	N	N	N	N
30		N	N	N	N	N	SM	N	SM	SM	SM	N	N	N	N	SM	N
32		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
34		N	N	N	N	N	N	SM	SM	N	N	SM	N	SM	N	N	N
35		N	N	N	N	N	N	N	N	N	N	N	N	N	N	SM	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	SM
40		N	N	N	N	N	N	N	N	N	SM	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	SM	N	N	N	SM	N	N	N	N	N	SM
47		N	N	N	N	N	N	N	N	SM	N	N	N	N	N	N	N
3	Controls	N	N	N	N	N	CM	CM	CM	CM	SM	SM	SM	SM	SM	SM	N
8		N	N	N	N	N	SM	SM	N	CM	SM	N	SM	N	N	N	SM
11		N	N	N	N	N	SM	N	N	SM	SM	SM	SM	SM	N	N	N
13		N	N	N	N	N	SM	N	SM	SM	SM	SM	N	CM	N	N	N
25		N	N	N	N	N	N	CM	SM	CM	CM	CM	CM	N	N	SM	N
38		N	N	N	N	SM	N	N	SM	SM	CM	CM	SM	CM	N	N	SM
44		N	N	N	N	N	N	SM	N	N	SM	SM	N	CM	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	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
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	D	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	D	D,Ab	D	D,Ab	D,Ab	N	D,Ab	N	N	N	N	N	N
32		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33		N	N	N	Ab	N	N	N	N	N	N	N	N	N	N	N	N
34		N	N	N	N	N	N	N	D,Ab	D,Ab	N	N	D,Ab	Ab	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	Controls	N	N	N	N	N	D,Ab	D,Ab	D	D,Ab	D	D	D	D	D	D	D
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	D	D	N	N	N	N	N	N	N	N	N	N
25		N	N	N	N	N	N	N	N	N	N	D,Ab	N	N	N	N	N
38		N	N	N	N	N	D,Ab	D	D	N	N	N	D,Ab	D	D	D	D
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	Vaccinates	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
2		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14		-	-	-	+	-	+	+	-	-	-	-	-	-	-	-	-
16		-	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-
19		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30		-	-	-	+	+	+	+	-	-	-	-	-	-	-	-	-
32		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33		-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
34		-	-	-	+	+	+	-	+	+	-	-	-	-	-	-	-
35		-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-
36		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39		-	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-
40		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
41		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
43		-	-	-	-	+	+	+	+	-	-	-	-	-	-	-	-
47		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
3	Controls	-	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
8		-	-	-	+	+	+	+	-	-	-	-	-	-	-	-	-
11		-	-	-	+	+	+	+	+	-	-	-	-	-	-	-	-
13		-	-	-	+	+	+	+	+	-	-	-	-	-	-	-	-
25		-	-	-	+	+	+	+	+	+	-	-	-	-	-	-	-
38		-	-	-	+	+	+	+	+	-	-	-	-	-	-	-	-
44		-	-	-	-	+	+	+	+	-	-	-	-	-	-	-	-

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

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>298 horses received 2 doses intramuscularly 3 to 4 weeks apart for primary immunization. 254 horses received 1 dose intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>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.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed immediately following vaccination and then daily for 3 days post-vaccination</td></tr>
<tr><td>Results</td><td>Doses are reported due to difference in vaccination schedule.

<table>
<tr><th>Score</th><th># of Cases</th><th>% of Total</th></tr>
<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>
</table>
Total # of Doses administered = 850

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.</td></tr>
<tr><td>USDA Approval Date</td><td>February 8, 2006</td></tr>
</table>