Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4845.26
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fluvac Innovator 5 - No distributor specified
Date of Compilation Summary	January 10, 2023

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	Tetanus Toxoid
Study Purpose	Efficacy against *Clostridum tetani* in horses
Product Administration	
Study Animals	Guinea pigs
Challenge Description	NA
Interval observed after challenge	NA
Results	Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.114.
USDA Approval Date	04/19/1984

Study Type	Efficacy
Pertaining to	Eastern Equine Encephalomyelitis Virus (EEE)
Study Purpose	Efficacy against EEE
Product Administration	Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements
Study Animals	Guinea pigs
Challenge Description	NA
Interval observed after challenge	NA
Results	Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2).
USDA Approval Date	NA

Study Type	Efficacy
Pertaining to	Western Equine Encephalomyelitis Virus (WEE)
Study Purpose	Efficacy against WEE
Product Administration	Each product serial is tested in accordance with 9 CFR 113.207(b)(2) requirements
Study Animals	Guinea pigs
Challenge Description	NA
Interval observed after challenge	NA
Results	Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.207(b)(2).
USDA Approval Date	NA

Study Type	Efficacy
Pertaining to	Equine Herpesvirus Type 1 and Type 4 (EHV 1 and EHV 4)
Study Purpose	To demonstrate efficacy against EHV 1 and EHV 4
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 30, 1997

Study Type	Efficacy
Pertaining to	Equine Influenza Virus (EIV)
Study Purpose	To demonstrate efficacy against EIV
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 05, 2001

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Equine Influenza Virus</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate duration of efficacy against Influenza virus</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 21 days apart</td></tr>
<tr><td>Study Animals</td><td>15 vaccinated and 15 control horses, 11-12 months of age, and seronegative to equine influenza virus (HAI antibody titers <1:8).</td></tr>
<tr><td>Challenge Description</td><td>Equine Influenza Virus – Strain Influenza A/equi-2/Ohio/03 (Clade 1) administered 93 days after 2nd vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed daily following challenge for 21 days for signs of clinical disease, and fever.</td></tr>
<tr><td>Results</td><td>A horse was considered affected if at least one occurrence of coughing or mucopurulent nasal discharge was displayed.

Table 1: Number of Animals with Clinical Disease
<table>
<tr><th>Treatment</th><th>N</th><th>Number of Animals with Clinical Disease</th></tr>
<tr><td>Vaccinates (Group 1)</td><td>15</td><td>8</td></tr>
<tr><td>Controls (Group 2)</td><td>15</td><td>15</td></tr>
</table>
Individual animal data can be found below for the presence of clinical disease, rectal temperatures, and presence of each clinical sign.</td></tr>
<tr><td>USDA Approval Date</td><td>June 24, 2009</td></tr>
</table>

Table 2
Summary of Clinical Signs in Study Animals Challenged

Assigned Number	Group	Coughing[a]	Nasal Discharge[b]	Clinical Disease[c]	Fever[d]
1	1	N	N	N	Y
2	1	N	Y	Y	N
4	1	N	N	N	N
5	1	N	Y	Y	N
6	1	Y	N	Y	N
7	1	N	N	N	N
10	1	N	N	N	N
17	1	N	Y	Y	N
19	1	N	N	N	N
21	1	Y	N	Y	N
22	1	N	N	N	N
27	1	N	Y	Y	N
30	1	Y	Y	Y	N
31	1	N	Y	Y	N
32	1	N	N	N	N
3	2	Y	Y	Y	Y
8	2	Y	Y	Y	N
9	2	Y	N	Y	N
11	2	Y	N	Y	N
14	2	Y	Y	Y	N
15	2	Y	Y	Y	N
16	2	Y	Y	Y	N
18	2	Y	Y	Y	Y
20	2	Y	Y	Y	Y
23	2	Y	Y	Y	N
24	2	Y	Y	Y	Y
25	2	Y	Y	Y	N
26	2	Y	Y	Y	Y
28	2	Y	Y	Y	N
29	2	Y	N	Y	N

[a] Animal displayed at least 1 instances of coughing

[b] Animal displayed at least 1 instances of mucopurulent nasal discharge

[c] Animal has meet case definition for disease by meeting any of the two clinical criteria (1 occurrences of coughing, 1 occurrences of mucopurulent nasal discharge)

[d] Animal displayed at least 1 instance of fever (> 103.5ºF and 1ºF above baseline).

Group 1 = Vaccinates

Group 2 = Controls

Table 3
Clinical Observations of Coughing in Study Animals Challenged

Assigned Number	Group	-2 DPC	-1 DPC	0 DPC	1 DPC	2 DPC	3 DPC	4 DPC	5 DPC	6 DPC	7 DPC	8 DPC	9 DPC	10 DPC	11 DPC	12 DPC
1	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
2	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
4	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
5	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
6	1	A	A	A	A	A	C1	A	A	A	A	A	A	A	A	A
7	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
10	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
17	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
19	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
21	1	A	A	A	A	A	C1	C1	A	A	A	A	A	A	A	A
22	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
27	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
30	1	A	A	A	A	A	A	A	A	A	A	A	A	C1	A	A
31	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
32	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
3	2	A	A	A	A	A	C2	C1	C1	A	C2	C2	C2	C2	A	A
8	2	A	A	A	A	A	A	A	A	C1	C2	C2	A	A	C1	A
9	2	A	A	A	A	A	A	A	C1	A	A	C1	A	A	A	A
11	2	A	A	A	A	A	C2	A	A	A	C2	C1	A	C1	A	A
14	2	A	A	A	A	A	A	C1	A	A	A	A	A	A	A	A
15	2	A	A	A	A	A	A	A	A	A	C2	A	A	C1	A	A
16	2	A	A	A	A	A	C2	A	A	A	C1	A	A	C1	A	A
18	2	A	A	A	A	A	A	C1	A	A	A	A	A	C1	A	A
20	2	A	A	A	A	A	A	C1	A	A	C1	A	A	A	A	A
23	2	A	A	A	A	A	A	A	A	A	C2	A	C1	C1	A	A
24	2	A	A	A	A	A	A	A	A	A	A	A	A	C2	A	A
25	2	A	A	A	A	C1	C1	A	A	A	C1	A	C1	C1	C1	A
26	2	A	A	A	A	A	C1	C1	A	C1	C2	C1	C2	C1	C2	C2
28	2	A	A	A	A	A	C2	A	C1	A	A	A	C2	C2	A	A
29	2	A	A	A	A	A	A	C1	A	A	A	A	A	A	A	A

DPC = Days post challenge

Group 1 = Vaccinates

Group 2 = Controls

Clinical Codes for Coughing
(highlighted in yellow)

C1: Infrequent Coughing

C2: Frequent Coughing

Table 3 continued

Assigned Number	13 DPC	14 DPC	15 DPC	16 DPC	17 DPC	18 DPC	19 DPC	20 DPC	21 DPC
1	A	A	A	A	A	A	A	A	A
2	A	A	A	A	A	A	A	A	A
4	A	A	A	A	A	A	A	A	A
5	A	A	A	A	A	A	A	A	A
6	A	A	A	A	A	A	A	A	A
7	A	A	A	A	A	A	A	A	A
10	A	A	A	A	A	A	A	A	A
17	A	A	A	A	A	A	A	A	A
19	A	A	A	A	A	A	A	A	A
21	A	A	A	A	A	A	A	A	A
22	A	A	A	A	A	A	A	A	A
27	A	A	A	A	A	A	A	A	A
30	A	A	A	A	A	A	A	A	A
31	A	A	A	A	A	A	A	A	A
32	A	A	A	A	A	A	A	A	A
3	A	A	A	A	A	A	A	A	A
8	A	A	A	A	A	A	A	A	A
9	A	A	A	A	A	A	A	A	A
11	A	A	A	A	A	A	A	A	A
14	A	A	A	A	A	A	A	A	A
15	A	A	A	A	A	A	A	A	A
16	A	A	A	A	A	A	A	A	A
18	A	A	A	A	A	A	A	A	A
20	A	A	A	A	A	A	A	A	A
23	A	A	A	A	A	A	A	A	A
24	A	A	A	A	A	A	A	A	A
25	A	A	A	A	A	A	A	A	A
26	A	C2	C1	A	A	A	A	A	A
28	A	A	A	A	A	A	A	A	A
29	A	A	A	A	A	A	A	A	A

DPC = Days post challenge

Group 1 = Vaccinates

Group 2 = Controls

Clinical Codes for Coughing (highlighted in yellow)

C1: Infrequent Coughing

C2: Frequent Coughing

Table 4
Clinical Observations of Mucopurulent Nasal Discharge in Study Animals Challenged

Assigned Number	Group	-2 DPC	-1 DPC	0 DPC	1 DPC	2 DPC	3 DPC	4 DPC	5 DPC	6 DPC	7 DPC	8 DPC	9 DPC	10 DPC	11 DPC	12 DPC
1	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
2	1	A	A	A	A	A	A	M1	A	A	A	A	A	A	A	A
4	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
5	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
6	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
7	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
10	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
17	1	A	A	A	A	A	A	A	A	A	A	A	M1	A	A	A
19	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
21	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
22	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
27	1	A	A	A	A	A	A	A	A	A	M1	A	A	A	A	A
30	1	A	A	A	A	A	A	A	A	A	A	A	A	M1	M1	A
31	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
32	1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
3	2	A	A	A	A	A	A	A	M2	M1	A	M1	A	M1	A	M1
8	2	A	A	A	A	A	A	A	M1	A	A	M1	M1	M1	M1	A
9	2	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
11	2	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
14	2	A	A	A	A	A	A	A	A	A	M1	A	A	M1	A	A
15	2	A	A	A	A	A	A	M1	A	M1	A	A	A	M1	A	A
16	2	A	A	A	A	A	A	M1	M1	M1	A	A	A	A	M1	A
18	2	A	A	A	A	A	A	A	A	A	A	M1	A	M1	A	A
20	2	A	A	A	A	A	A	A	M1	A	M1	M1	A	M1	A	A
23	2	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
24	2	A	A	A	A	A	A	M1	M1	A	A	M1	M1	M1	M1	A
25	2	A	A	A	A	A	A	A	A	A	A	A	M1	M1	A	A
26	2	A	A	A	A	A	A	A	A	M2	A	A	M1	M1	A	A
28	2	A	A	A	A	A	A	A	A	A	A	M1	A	M1	A	A
29	2	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A

DPC = Days post challenge

Group 1 = Vaccinates

Group 2 = Controls

Clinical Codes for Mucopurulent Nasal Discharge (highlighted in yellow)

M1: Mild Discharge

M2: Moderate Discharge

M3: Severe Discharge

Table 4 continued

Assigned Number	13 DPC	14 DPC	15 DPC	16 DPC	17 DPC	18 DPC	19 DPC	20 DPC	21 DPC
1	A	A	A	A	A	A	A	A	A
2	A	A	A	A	A	A	A	A	A
4	A	A	A	A	A	A	A	A	A
5	M1	A	A	A	A	A	A	A	A
6	A	A	A	A	A	A	A	A	A
7	A	A	A	A	A	A	A	A	A
10	A	A	A	A	A	A	A	A	A
17	A	A	A	A	A	A	A	A	A
19	A	A	A	A	A	A	A	A	A
21	A	A	A	A	A	A	A	A	A
22	A	A	A	A	A	A	A	A	A
27	A	A	A	A	A	M1	A	A	A
30	A	A	M1	A	A	A	A	A	A
31	A	A	A	A	A	A	M1	A	A
32	A	A	A	A	A	A	A	A	A
3	M2	M2	M2	A	M1	A	A	A	A
8	A	A	A	A	A	A	A	A	A
9	A	A	A	A	A	A	A	A	A
11	A	A	A	A	A	A	A	A	A
14	A	A	A	A	A	A	A	A	A
15	A	A	A	A	A	A	A	A	A
16	A	A	A	A	A	A	A	A	A
18	A	A	A	A	A	A	A	A	A
20	A	A	A	A	A	A	A	A	A
23	M1	A	A	A	A	A	A	A	A
24	M1	A	A	A	A	A	A	A	A
25	M1	A	A	A	A	A	A	A	A
26	A	A	A	A	A	A	A	A	A
28	A	A	A	A	M1	A	A	A	A
29	A	A	A	A	A	A	A	A	A

DPC = Days post challenge

Group 1 = Vaccinates

Group 2 = Controls

Clinical Codes for Mucopurulent Nasal Discharge (highlighted in yellow)

M1: Mild Discharge

M2: Moderate Discharge

M3: Severe Discharge

Table 5
Daily Rectal Temperatures (°F) in Horses Challenged

Assigned Number	Group	-2 DPC	-1 DPC	0 DPC	Baseline	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC
1	1	100.6	100.0	100.0	100.2	101.3	100.8	103.5	99.7	99.9	99.1	100.4	99.9	100.6	99.9	100.2	99.9
2	1	101.1	100.4	100.8	100.8	100.0	100.9	101.3	100.4	100.8	100.6	100.8	100.8	101.3	100.8	100.6	99.5
4	1	100.6	100.6	100.4	100.5	99.5	101.1	100.6	100.8	100.4	100.0	99.7	100.0	100.2	101.7	100.2	99.7
5	1	100.9	100.8	101.1	100.9	100.8	102.7	100.8	100.0	100.4	99.9	100.0	99.9	100.8	100.2	100.9	100.6
6	1	100.0	99.7	99.7	99.8	99.9	100.2	99.7	100.2	100.0	99.9	100.0	99.5	99.9	100.2	99.7	99.5
7	1	99.9	100.0	100.4	100.1	100.2	100.0	100.9	99.7	99.9	99.5	100.0	99.5	98.8	100.0	100.4	99.5
10	1	100.4	100.6	100.0	100.3	99.9	100.2	100.4	99.5	103.1	102.6	101.8	100.4	100.2	99.9	100.6	100.0
17	1	99.7	100.0	100.0	99.9	99.5	100.4	100.2	99.7	100.0	100.0	99.9	99.7	100.4	100.6	100.0	100.0
19	1	99.7	100.2	99.5	99.8	100.0	100.0	100.2	99.3	100.6	99.5	99.7	100.0	100.0	100.0	100.2	100.0
21	1	100.4	100.2	99.9	100.2	99.7	100.6	100.6	100.4	100.0	99.5	100.0	100.0	100.2	99.9	100.2	100.0
22	1	100.0	99.9	100.0	100.0	99.9	100.0	99.5	100.4	100.0	99.1	99.7	99.5	100.0	100.0	100.4	99.7
27	1	100.4	100.0	99.9	100.1	100.4	100.2	100.6	99.7	100.4	100.0	100.4	100.2	100.8	100.0	100.0	100.0
30	1	100.6	99.9	99.7	100.0	100.0	100.6	99.9	99.5	99.9	99.9	99.9	100.4	100.2	100.0	100.0	99.9
31	1	99.7	100.0	100.2	100.0	100.6	99.1	100.8	99.5	99.7	99.3	100.2	99.7	100.4	100.0	99.7	99.5
32	1	100.8	100.4	100.2	100.5	100.0	100.6	99.9	99.7	100.4	100.0	100.4	100.0	100.6	100.4	100.6	99.9
3	2	100.9	100.4	100.0	100.5	100.0	102.7	103.5	101.7	100.8	100.0	103.5	101.8	100.6	100.0	100.0	99.9
8	2	100.4	99.9	99.1	99.8	99.1	100.2	99.9	100.0	100.0	100.2	100.6	102.7	100.8	100.6	100.8	99.9
9	2	100.0	99.9	100.0	100.0	100.2	100.9	100.6	99.7	100.6	100.0	100.0	100.4	100.9	99.5	99.9	100.0
11	2	99.9	99.5	99.9	99.7	99.7	100.4	101.7	100.0	102.0	100.8	100.4	100.4	100.6	99.9	99.9	100.4
14	2	99.9	99.7	99.7	99.7	99.7	100.0	100.0	100.0	99.1	100.4	100.0	100.0	100.6	99.5	99.9	99.7
15	2	100.6	100.2	100.6	100.5	100.0	100.8	101.8	99.9	100.6	99.9	100.6	100.9	100.8	100.6	99.9	99.9
16	2	100.8	100.6	100.4	100.6	100.2	101.5	102.9	100.0	100.8	100.6	100.8	100.4	100.9	100.2	100.6	100.2
18	2	100.0	100.0	100.0	100.0	100.4	103.5	101.7	98.8	103.5	100.9	100.4	99.7	100.4	100.0	100.6	100.0
20	2	100.9	100.6	100.4	100.6	99.9	100.9	101.1	99.7	100.6	101.3	100.6	100.0	100.0	100.8	101.3	101.3
23	2	99.7	99.9	99.7	99.7	99.1	99.9	101.5	99.7	100.4	100.6	100.4	99.9	100.4	99.9	100.4	99.7
24	2	100.6	99.9	100.0	100.2	99.3	102.6	100.9	100.2	102.9	102.0	104.7	102.6	101.7	100.8	100.6	99.7
25	2	100.8	100.4	100.0	100.4	100.4	102.7	100.4	99.9	100.0	100.9	100.4	99.9	100.2	99.7	100.0	99.9
26	2	99.9	99.7	99.9	99.8	99.9	101.5	104.4	101.5	101.5	100.9	102.9	102.2	103.3	101.7	101.8	100.2
28	2	100.0	100.0	99.9	100.0	99.5	100.2	101.7	100.6	101.5	100.6	100.2	99.7	100.4	99.7	99.9	99.3
29	2	99.7	100.4	100.4	100.2	100.0	101.8	102.7	101.1	102.4	100.8	100.6	100.8	100.2	99.9	100.2	99.5

Rectal temperatures were recorded in °C, however they have been converted to °F.

Temperatures greater than or equal to 103.5°F are fever and highlighted in yellow

DPC = Days post challenge

Group 1 = Vaccinates

Group 2 = Controls

Table 5 continued

Assigned Number	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC
1	99.1	99.7	99.7	99.9	100.4	99.5	100.4	99.9	99.9
2	100.4	100.8	99.9	100.4	101.5	101.8	100.8	100.0	100.4
4	99.5	99.5	100.0	100.4	100.0	99.9	100.4	100.0	100.0
5	100.6	100.2	99.9	100.6	99.5	99.5	100.0	99.9	99.9
6	98.8	100.0	99.3	99.5	99.9	99.3	99.7	99.9	99.0
7	99.5	99.9	99.9	99.7	99.3	100.0	100.4	100.0	100.0
10	99.9	100.2	100.4	101.1	100.2	100.6	100.2	100.0	99.9
17	99.7	100.2	99.9	99.9	99.9	101.3	100.6	99.5	100.0
19	99.7	99.5	99.9	100.0	99.7	100.0	100.0	100.6	100.2
21	99.5	100.2	100.2	100.4	99.7	99.9	99.7	100.4	99.9
22	100.0	100.0	99.9	99.7	100.2	99.7	100.2	99.7	99.7
27	99.9	100.8	99.5	100.0	100.0	100.2	100.6	100.6	100.4
30	99.9	99.9	99.9	99.9	99.1	99.7	100.4	100.4	99.3
31	100.0	99.5	99.1	100.2	99.7	99.5	100.0	100.0	100.0
32	99.9	99.9	99.5	99.9	100.0	100.0	100.6	100.4	99.5
3	99.7	99.5	99.7	100.2	99.9	100.0	100.6	99.9	100.0
8	99.9	99.5	99.3	100.4	99.7	99.7	100.9	100.4	99.1
9	99.7	99.5	99.5	99.7	99.1	100.0	100.0	99.3	99.5
11	99.0	99.9	99.9	100.0	99.7	99.5	100.6	100.2	100.0
14	99.7	99.7	99.7	99.7	99.5	99.9	100.0	99.7	100.2
15	99.0	100.0	99.9	100.2	99.9	102.2	100.8	100.8	100.6
16	99.5	100.6	100.0	99.5	100.2	100.4	100.6	100.0	100.0
18	100.0	100.4	100.0	100.9	100.0	100.2	100.0	100.2	100.0
20	100.0	100.8	99.5	100.2	100.0	103.5	100.4	99.1	100.8
23	99.9	99.9	99.5	99.7	100.0	100.6	100.0	99.7	99.5
24	99.5	99.9	99.5	99.9	99.9	99.9	100.0	99.9	99.7
25	99.7	100.0	99.9	100.4	99.9	100.0	100.0	99.9	99.7
26	99.9	99.5	99.7	99.9	99.3	99.5	99.1	99.7	99.5
28	99.3	100.0	99.7	100.2	99.7	99.1	100.0	99.9	99.5
29	100.0	100.0	100.9	100.9	100.0	100.4	100.6	100.4	100.4

Rectal temperatures were recorded in °C, however they have been converted to °F.
Temperatures greater than or equal to 103.5°F are fever and highlighted in yellow.

DPC = Days post challenge
Group 1 = Vaccinates
Group 2 = Controls

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstration of safety under typical field conditions
Product Administration	
Study Animals	809 horses
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	September 26, 2001

<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>Determine safety of product in horses 3 months of age in typical field conditions</td></tr>
<tr><td>Product Administration</td><td>2 doses administered intramuscularly 3 to 4 weeks apart</td></tr>
<tr><td>Study Animals</td><td>247 foals approximately 3 months of age were enrolled at 3 different geographical sites</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for immediate post-vaccination reactions 30 minutes after vaccination, and observed daily for 21 days after each vaccination</td></tr>
<tr><td>Results</td><td>Two hundred and forty-three foals (98.4%) completed the study. Four (3) horses did not complete the study for reasons unrelated to the vaccine. There were no immediate systemic or local reactions using 490 doses of product.

<u>Table 1: Frequency Distribution of Abnormal Health Events in Vaccinates:</u>

<table>
<tr><th>Number of Vaccinations</th><th>Abnormal Health Event</th><th>Number (Percent of Vaccinations)</th></tr>
<tr><td rowspan="12">490 Vaccinations</td><td>Cough</td><td>4 (0.82%)</td></tr>
<tr><td>Depression</td><td>1 (0.20%)</td></tr>
<tr><td>Diarrhea</td><td>3 (0.61%)</td></tr>
<tr><td>Fever</td><td>5 (1.02%)</td></tr>
<tr><td>Hematoma</td><td>1 (0.20%)</td></tr>
<tr><td>Lameness</td><td>3 (0.61%)</td></tr>
<tr><td>Leukocytosis</td><td>1 (0.20%)</td></tr>
<tr><td>Lymphadenopathy</td><td>1 (0.20%)</td></tr>
<tr><td>Nasal Discharge</td><td>3 (0.61%)</td></tr>
<tr><td>Pneumonia</td><td>5 (1.02%)</td></tr>
<tr><td>Skin Lesion NOS*</td><td>3 (0.61%)</td></tr>
<tr><td>Skin Edema</td><td>2 (0.41%)</td></tr>
</table>
*Not otherwise specified

Additional data is provided on the next page.</td></tr>
<tr><td>USDA Approval Date</td><td>May 02, 2016</td></tr>
</table>

Table 2: Abnormal Health Events and Relation to Investigational Veterinary Product (IVP) for Individual Animals

Animal #	Start Day	End Day	Abnormal Health Event	Outcome
ND001	2	4	Skin Lesion NOS*	Resolved
KS078	2	2	Diarrhea	Resolved
KY001	29	32	Lameness	Resolved
	29	29	Fever	Resolved
KY002	13	29	Pneumonia	Resolved
KY027	34	46	Lameness	Resolved
KY034	25	28	Nasal Discharge	Resolved
KY035	25	28	Cough	Resolved
	25	28	Leukocytosis	Resolved
	41	41	Fever	Resolved
	41	42	Leukocytosis	Resolved
	41	67	Pneumonia	Resolved
KY037	13	15	Nasal Discharge	Resolved
	45	46	Skin Lesion NOS*	Resolved
KY038	22	23	Lymphadenopathy	Resolved
KY041	25	97	Cough	Resolved
	25	97	Pneumonia	Resolved
KY042	29	29	Fever	Resolved
KY043	29	29	Fever	Resolved
KY044	23	26	Diarrhea	Resolved
	23	24	Depression	Resolved
KY045	29	29	Diarrhea	Resolved
KY053	6	8	Lameness	Resolved
KY058	6	13	Hematoma	Resolved
KY059	29	60	Pneumonia	Resolved
KY061	9	14	Skin Edema	Resolved
KY062	10	12	Skin Edema	Resolved
KY063	29	60	Pneumonia	Resolved
KY083	34	48	Skin Lesion NOS*	Resolved
KY089	22	24	Cough	Resolved
	22	24	Nasal Discharge	Resolved
KY102	7	11	Cough	Resolved
	7	7	Fever	Resolved

* NOS = Not otherwise specified