Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4X41.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovi-Shield Gold One-Shot - No distributor specified Bovi-Shield Gold One-Shot - Zoetis Industria Produtos Veterinarios Ltda. Bovi-Shield Gold One-Shot - Zoetis Mexico Bovi-Shield Gold One-Shot - Zoetis Russia BoviShield Gold - No distributor specified BoviShield Gold One Shot - Zoetis Russia BoviShield Gold One Shot - Zoetis South Africa Ltd
Date of Compilation Summary	August 18, 2022

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	Bovine viral diarrhea virus type 1 (BVDV1)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BVDV1
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV1b NY-1
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	06/27/2005

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Viral Diarrhea Virus, type 1 (BVDV 1)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate at least 9-month duration of immunity against respiratory disease caused by BVDV 1</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously (SC)</td></tr>
<tr><td>Study Animals</td><td>20 vaccinates and 10 control calves, 5 months of age and seronegative for BVDV1 and BVDV 2 (serum neutralizing antibody titer <1:2)</td></tr>
<tr><td>Challenge Description</td><td>BVDV 1 virus (non-cytopathic type 1b strain New York-1) administered 279 days following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for 14 days following challenge. Blood samples were collected for virus isolation on Study days 278 to 293, excluding 279 and white blood cell count on Study days 277 through 289, excluding 280.</td></tr>
<tr><td>Results</td><td>Calves were considered affected by BVDV respiratory disease if they developed leukopenia defined as 40% decrease in white blood cell from pre-challenge baseline. The number of animals with BVD Viremia was also determined following challenge.

<table>
<tr><th></th><th>Viremia</th><th>Leukopenia</th></tr>
<tr><td>Controls</td><td>9/10 (90%)</td><td>7/10 (70%)</td></tr>
<tr><td>Vaccinates</td><td>0/20 (0%)</td><td>0/20 (0%)</td></tr>
</table>

See attached pages for individual animal data.</td></tr>
<tr><td>USDA Approval Date</td><td>01/26/2011</td></tr>
</table>

Virus Isolation from Blood (Viremia)															
Animal ID	**Study Days (Challenge was on Day 279)**														
	278	**280**	**281**	**282**	**283**	**284**	**285**	**286**	**287**	**288**	**289**	**290**	**291**	**292**	**293**
CONTROLS															
75	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No
78	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No
82	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No
87	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
88	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No
91	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No
98	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
99	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No
102	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No
103	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No
VACCINATES															
73	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
74	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
76	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
77	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
79	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
83	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
84	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
85	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
90	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
92	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
94	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
95	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
96	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
100	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
101	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
104	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
105	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
107	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
108	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
109	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Yes=positive for BVD 1 virus isolation; No=negative for BVD 1 virus isolation

Leukopenia (40% drop in WBC* from baseline)									
Animal ID	**Study Days (Challenge was on day 279)**								
	281	**282**	**283**	**284**	**285**	**286**	**287**	**288**	**289**
CONTROLS									
75	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No
78	No	Yes	No	No	No	No	No	No	No
82	No	No	No	No	No	No	No	No	No
87	No	No	No	No	No	No	No	No	No
88	No	No	No	No	No	Yes	No	No	No
91	No	Yes	No	No	No	No	No	No	No
98	No	No	No	No	Yes	No	No	No	No
99	No	Yes	No	No	No	No	No	No	No
102	No	Yes	No	No	No	No	No	No	No
103	No	No	No	No	No	No	No	No	No
VACCINATES									
73	No	No	No	No	No	No	No	No	No
74	No	No	No	No	No	No	No	No	No
76	No	No	No	No	No	No	No	No	No
77	No	No	No	No	No	No	No	No	No
79	No	No	No	No	No	No	No	No	No
83	No	No	No	No	No	No	No	No	No
84	No	No	No	No	No	No	No	No	No
85	No	No	No	No	No	No	No	No	No
90	No	No	No	No	No	No	No	No	No
92	No	No	No	No	No	No	No	No	No
94	No	No	No	No	No	No	No	No	No
95	No	No	No	No	No	No	No	No	No
95	No	No	No	No	No	No	No	No	No
100	No	No	No	No	No	No	No	No	No
101	No	No	No	No	No	No	No	No	No
104	No	No	No	No	No	No	No	No	No
105	No	No	No	No	No	No	No	No	No
107	No	No	No	No	No	No	No	No	No
108	No	No	No	No	No	No	No	No	No
109	No	No	No	No	No	No	No	No	No

* WBC = Whole blood cells; Yes=presence of Leukopenia; No=no presence of Leukopenia

White Blood Cell Counts (x 1000 cells/µL)												
Animal ID	**Study Days (Challenge was on Day 279)**											
	277	**278**	**279**	**281**	**282**	**283**	**284**	**285**	**286**	**287**	**288**	**289**
CONTROLS												
75	11.1	10.6	10.4	10.8	5.8	6.2	6.3	6.2	5.2	5.8	7.1	8.1
78	10.8	8.4	9.3	10.0	5.4	6.4	7.5	6.8	6.1	6.8	9.2	7.5
82	10.6	8.9	9.1	9.4	7.4	8.0	7.1	6.4	7.7	7.5	9.3	9.0
87	9.0	7.9	7.8	7.9	6.6	6.0	5.7	5.9	5.9	6.4	8.4	7.1
88	10.4	10.7	9.3	8.4	6.7	6.3	6.5	6.5	5.6	8.7	10.2	8.5
91	11.6	10.8	10.8	11.6	5.7	7.8	8.3	8.0	8.3	10.9	10.8	11.7
98	9.9	8.7	9.8	10.4	6.1	6.0	6.9	5.6	6.1	9.1	10.8	10.9
99	8.5	8.7	8.1	9.0	4.8	5.5	5.9	5.6	6.1	5.9	6.5	7.5
102	11.6	9.9	9.4	10.6	4.9	7.5	10.8	6.7	7.1	8.7	9.4	9.4
103	8.8	7.6	7.4	9.1	6.4	5.4	5.1	5.3	5.6	7.3	9.0	8.6
VACCINATES												
73	8.0	7.5	6.8	7.2	6.9	5.9	5.7	6.6	7.0	8.1	8.9	7.6
74	10.4	10.8	10	10.7	12.5	11.9	9.6	9.1	9.4	10.3	11.4	11.3
76	11.0	10.0	10.5	10.8	12.1	12.2	11.9	11.4	12.3	12.6	11.0	11.5
77	12.1	12.3	11.7	11.2	11.0	9.4	9.0	9.2	9.9	12.4	10.5	11.3
79	16.5	14.6	14.8	15.3	15.3	13.5	12.8	12.6	13.4	16.2	19.0	13.8
83	10.8	10.1	10.5	12	11.5	10.1	10.4	13.2	13.6	15.2	15.1	14.3
84	15.0	11.2	10.0	10.5	10.6	11.4	11.0	11.3	12.6	12.6	13.7	11.9
85	11.3	10.7	11.2	12.7	11.0	9.6	9.6	10.2	10.3	13.2	13.3	11.6
90	9.7	10.5	10.0	10.2	10.2	10.3	8.3	9.2	9.7	10.2	10.1	9.5
92	12.0	10.8	11.6	11.2	10.6	8.6	9.3	9.8	11.7	12.6	12.4	11.7
94	10.1	9.1	9.0	10.7	11.2	8.2	8.8	10.3	10.6	11.9	12.5	11.4
95	12.9	13.1	11.6	12.6	11.1	11.6	11.2	11.0	11.5	11.9	11.2	10.8
96	14.2	15.1	15.7	17.2	13.8	12.3	11.3	13.6	15.5	16.2	15.9	14.5
100	8.1	8.0	8.0	8.5	8.1	8.5	8.0	8.8	8.9	9.4	9.0	8.1
101	10.9	10.0	9.5	10.4	12	9.5	8.9	8.8	10.9	10.9	12.2	11.4
104	12.8	10.8	10.6	12.3	11.6	12.2	11.6	10.8	12.6	15.0	14.4	14.4
105	11.7	9.1	10.5	10.8	11.5	10.9	9.6	11.1	10.5	10.7	10.3	9.3
107	11.8	11.4	11.4	12.6	9.8	9.7	9.0	9.4	11.8	12.2	13.2	11.9
108	14.3	13.5	12.2	12.3	11.6	11.9	12.2	14.3	14.1	14.1	14.6	13.8
109	13.5	12.3	11.8	11.7	11.7	12.4	11.8	12.9	13.2	13.2	13.9	12.9

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus type 2 (BVDV2)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BVDV2
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV2a strain 24515
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	06/27/2005

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Viral Diarrhea Virus, type 2 (BVDV2)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate at least 9-month duration of immunity against respiratory disease caused by BVDV2</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously (SC)</td></tr>
<tr><td>Study Animals</td><td>20 vaccinates and 10 control calves, 4 to 5 months of age and seronegative for BVDV1 and BVDV2 (serum neutralizing antibody titer <1:2)</td></tr>
<tr><td>Challenge Description</td><td>BVDV2 virus (non-cytopathic type 2a strain 24515) administered 280 days following vaccination (Study Day 280)</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for 16 days following challenge. Blood samples were collected for virus isolation on Study Days 279 and 281-294 and white blood cell count on days 278 through 294, excluding 281.</td></tr>
<tr><td>Results</td><td>Calves were considered affected by BVDV respiratory disease if they died or were humanely euthanized post-challenge. The number of animals that developed leukopenia (defined as 40% decrease in white blood cell from pre-challenge baseline) and BVD viremia was also determined following challenge. Abnormal clinical signs were also collected (an animal was considered abnormal if the clinical score was ≥ 2).
<table>
<tr><th></th><th>Mortality</th><th>Viremia</th><th>Leukopenia</th><th>Abnormal Clinical Signs</th></tr>
<tr><td>Controls</td><td>6/10 (60 %)</td><td>10/10 (100 %)</td><td>10/10 (100 %)</td><td>10/10 (1 %)</td></tr>
<tr><td>Vaccinates</td><td>1/20 (5 %)</td><td>1/20 (5 %)</td><td>2/20 (10 %)</td><td>5/20 (25 %)</td></tr>
</table>
See attached pages for individual animal data.</td></tr>
<tr><td>USDA Approval Date</td><td>01/26/2011</td></tr>
</table>

Mortality																	
Animal ID	**Study Days (Challenge was on Day 280)**																
	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296
CONTROLS																	
01	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-
04	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-	-	-	-
16	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-
18	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
26	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
28	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-
32	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
33	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-	-	-	-
35	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
36	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-	-	-	-
VACCINATES																	
01	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
05	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
06	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
07	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
08	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
10	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
11	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
12	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	-	-	-	-
13	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
15	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
17	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
19	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
20	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
21	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
23	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
24	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
25	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
30	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
31	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
34	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

Animal died or was humanely euthanized = YES; Animal survived = NO.
The yellow highlighted cells indicate “YES” and dead animal.
-: Animals 1, 12, 4, 16, 28, 33 and 36 died / were humanely euthanized during the challenge phase.

Abnormal Clinical Signs

Animal ID	Study Days (Challenge was on Day 280)																
	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296
CONTROLS																	
01	0	0	0	0	0	0	0	0	0	1	2	2	2	2	2	3	-
04	0	0	0	0	1	1	1	1	1	1	2	2	3	-	-	-	-
16	0	0	0	0	0	0	0	0	0	0	1	2	2	2	3	3	-
18	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	1	2	2	2	2	1	1
28	0	0	0	0	0	0	0	0	1	1	2	2	2	2	2	3	-
32	0	0	0	0	0	0	0	0	0	1	1	2	2	2	2	2	2
33	0	0	0	0	0	0	1	0	0	1	2	2	-	-	-	-	-
35	0	0	0	0	0	0	0	0	1	0	1	2	2	2	2	1	1
36	0	0	0	0	0	0	0	1	1	1	2	2	3	-	-	-	-
VACCINATES																	
02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
08	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	1	2	2	3	-	-	-	-
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1	1	1
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Clinical scoring:
0 = Normal animal, no clinical signs; 1 = Nonspecific clinical signs. Clinical signs as a whole are not specific for acute BVD infection and may include nasal discharge, abnormal respiration, and mild lethargy; 2 = Acute BVD clinical disease. Clinical signs as a whole are moderate in degree and specific for acute BVD infection and may include nasal discharge, abnormal respiration, lethargy, gauntness, ocular discharge, hypersalivation, diarrhea, dehydration, lameness and/or reluctance to move; 3 = Severe BVD clinical disease. Clinical signs as a whole are severe in degree and specific for acute BVD infection and may include nasal discharge, abnormal respiration, lethargy, gauntness, ocular discharge, hypersalivation, diarrhea, excessive bruising, dehydration, recumbency, lameness and/or reluctance to move.
The yellow highlighted cells indicate clinical score ≥ 1.
-: Animals 1, 4, 12, 16, 28, 33 and 36 died / were humanely euthanized during the challenge phase.

Virus Isolation															
Animal ID	Study Days (Challenge was on Day 280)														
	279	281	282	283	284	285	286	287	288	289	290	291	292	293	294
CONTROLS															
01	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO
04	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	-	-
16	NO	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO
18	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO
26	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO
28	NO	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	NO	YES	NO	NO
32	NO	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES	NO	NO
33	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	YES	NO	-	-	-
35	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO
36	NO	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	NO	-	-
VACCINATES															
02	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
05	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
06	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
07	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
08	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
10	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
11	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
12	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	-	-
13	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
15	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
17	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
19	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
20	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
21	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
23	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
24	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO
25	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
30	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
31	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
34	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

YES=positive for BVD 1 virus isolation; NO=negative for BVD 1 virus isolation

The yellow highlighted cells indicate “YES”.

-: Animals 1, 4, 12, 16, 28, 33 and 36 died / were humanely euthanized during the challenge phase.

Leukopenia (40% drop in WBC* from baseline)													
Animal ID	**Study Days (Challenge was on Day 280)**												
	282	**283**	**284**	**285**	**286**	**287**	**288**	**289**	**290**	**291**	**292**	**293**	**294**
CONTROLS													
01	NO	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES
04	NO	NO	NO	NO	NO	NO	NO	YES	YES	NO	NO	-	-
16	NO	NO	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
18	NO	NO	YES	YES	YES	YES	NO	NO	NO	NO	NO	NO	NO
26	NO	NO	YES	NO	YES	NO	NO	YES	YES	YES	YES	YES	YES
28	NO	NO	NO	YES	YES	NO	NO	NO	NO	NO	NO	NO	YES
32	NO	YES	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	YES
33	NO	NO	YES	YES	YES	YES	YES	YES	YES	YES	-	-	-
35	NO	NO	YES	NO	NO	NO	YES	YES	NO	NO	NO	NO	NO
36	NO	YES	NO	YES	YES	YES	YES	YES	YES	NO	YES	-	-
VACCINATES													
02	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
05	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
06	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
07	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
08	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
10	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
11	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
12	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	-	-
13	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
15	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
17	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
19	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
20	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
21	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
23	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
24	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
25	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
30	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
31	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
34	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

***** WBC = Whole blood cells; Yes=presence of Leukopenia; No=no presence of Leukopenia

The yellow highlighted cells indicate “YES”.

-: Animals 1, 4, 12, 16, 28, 33 and 36 died / were humanely euthanized during the challenge phase.

White Blood Cell Counts (x 1000 cells/μl)															
Animal ID	**Study Days (Challenge was on Day 280)**														
	278	**279**	**282**	**283**	**284**	**285**	**286**	**287**	**288**	**289**	**290**	**291**	**292**	**293**	**294**
CONTROLS															
01	12	10.0	15.4	6.0	5.9	6.7	5.7	5.9	5.6	4.1	3.7	3.7	3.9	2.8	2.7
04	9.6	9.7	20.5	12.3	8.7	8.7	6.7	8.0	7.8	4.0	5.3	5.8	7.8	-	-
16	12	13.3	14.4	10.4	6.2	6.9	7.5	6.8	5.9	4.5	4.2	3.8	4.2	4.1	3.2
18	9.1	7.5	9.1	5.8	4.0	4.1	3.9	4.3	5.9	5.5	6.1	6.6	6.1	7.3	8.0
26	10.4	13.5	15.7	9.1	7.0	7.5	6.7	7.4	7.7	6.6	5.6	5.0	5.5	6.9	7.3
28	8.1	11.2	11.7	10.4	6.1	5.9	5.9	6.7	6.3	6.6	6.0	6.4	7.1	6.2	5.0
32	14.8	15.0	16.2	7.2	9.3	10.0	9.3	9.9	7.9	5.6	5.0	5.8	5.1	4.9	4.0
33	10.6	12.5	11.5	7.5	6.1	5.5	5.5	5.7	3.4	2.4	2.5	2.9	-	-	-
35	14.7	13.8	14.8	8.9	7.4	9.0	8.5	8.8	8.2	7.5	9.7	10.0	10.2	11.3	12.2
36	10.2	9.7	11.0	5.1	9.8	5.7	5.4	5.3	5.5	3.9	4.8	6.1	4.8	-	-
VACCINATES															
02	11.2	12.0	12.6	12.4	12.3	9.0	10.2	10.0	11.7	13.2	13.2	12.8	12.6	12.8	13.7
05	13.4	11.8	13.9	14.8	13.2	13.7	14.1	14	12.4	16.5	16.2	15.4	13.9	15.0	16.4
06	8.7	9.0	12.5	8.1	6.5	5.4	5.7	8.9	11.3	12.1	12.6	9.9	11.2	11.5	9.5
07	13.6	14.2	15.1	14.6	13.6	13.3	13.3	14.1	15.1	13.2	14.6	15.5	14.4	15.9	15.8
08	13.6	12.8	19.9	19.7	17.8	16.2	16.8	17.5	15	15	16.3	16.3	16.5	14.9	18.1
10	9.2	8.0	10.7	9.4	5.6	5.6	7.1	8.3	9.6	9.9	9.8	9.0	9.5	10.7	11.0
11	10.6	10.5	12.5	13.0	13.3	11.7	11.3	11.3	11.3	12.0	12.6	12.6	12.8	12.8	13.7
12	10.2	9.4	10.1	13.2	10.5	10.2	10.2	11.2	14.6	15.5	6.5	6.2	8.5	-	-
13	9.5	11.5	11.5	10.7	9.9	8.3	9.0	9.6	11.2	12.1	11.9	11.3	11.3	10.5	10.3
15	13.2	14.3	13.6	13.7	10.2	7.6	9.1	12.1	14.5	14.2	13.8	12.7	11.4	12.3	12.3
17	11.4	12.3	13.1	12.7	12.7	10.1	10.0	11.8	14	13.2	12.8	14.4	12.8	13.8	14.6
19	9.7	9.6	13.1	11.9	10.2	8.9	9.6	8.9	9.7	10.5	11.1	11.6	11.6	11.5	11.3
20	12.8	14.2	13.4	14.6	15.8	15.6	12.5	14.1	13.4	12.4	13.8	12.8	15.8	14.0	11.5
21	13.3	14.6	15.7	15.3	15.3	15.7	16.2	15.1	15.1	14.9	14.8	14.0	15.2	14.8	15.3
23	8.3	10.2	11.9	10.8	10.9	11.2	11.0	11.3	12.7	14.1	14.3	12.7	11.6	10.8	10.8
24	12.2	10.7	12.5	12.2	9.3	8.8	11.8	12.5	13.9	14.2	15.8	12.7	13.1	14.3	10.8
25	17.2	17.4	17	15.6	17.7	16.1	15	14.1	15.5	17.9	16.7	16.7	17.0	17.3	17.9
30	11.5	10.7	11.6	9.0	7.0	7.4	7.4	9.1	10.8	12.0	11.8	11.3	11.0	10.9	11.7
31	9.6	8.6	9.3	8.8	7.5	5.9	6.9	8.0	8.7	10.0	11.4	9.2	10.0	10.1	10.5
34	11.1	11.1	13.3	12.2	8.6	10.1	10.5	11.9	14.6	14.8	16.4	16.1	15.7	14.6	16.1

-: Animals 1, 4, 12, 16, 28, 33 and 36 died / were humanely euthanized during the challenge phase.

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus type 1 (BVDV1)
Study Purpose	Demonstrate efficacy against viremia caused by BVDV1
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV type 1b strain New York-1
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	01/26/2011

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus type 2 (BVDV2)
Study Purpose	Demonstrate efficacy against viremia caused by BVDV2
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV type 2a Strain 24515
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	01/26/2011

Study Type	Efficacy
Pertaining to	Infectious bovine rhinotracheitis (IBR) virus
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR virus
Product Administration	One dose administered subcutaneously
Study Animals	17 vaccinated and 17 control calves, six to seven months of age, seronegative to IBR virus
Challenge Description	IBR virus administered 28 days post-vaccination
Interval observed after challenge	Animals were observed daily for 14 days following challenge (Study Day 29-Study Day 42)
Results	Presence of absence of IBR disease was the efficacy variable. IBR disease was defined as whether an animal ever exhibited one of the following clinical signs: depression, mucopurulent nasal discharge, and/or increased respiratory effort and sounds. IBR disease: Controls: 17/17 (100%) Vaccinates: 0/17 (0%) See individual data attached.
USDA Approval Date	July 26, 2012

IBR Disease by Treatment, Day and Animal

Controls

Animal	Study Day															
	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
15	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No	No	No
18	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
27	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
28	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No
30	No	No	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No
31	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
74	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
77	No	No	No	No	No	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No
80	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
82	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No
84	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
85	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No
89	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	No	No	No	No
90	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No
91	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
92	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No
93	No	No	No	No	No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No

Vaccinates

Animal	Study Day															
	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
11	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
19	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
20	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
22	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
24	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
25	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
32	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
33	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
34	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
44	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
57	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
58	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
67	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
73	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
75	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
79	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
94	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Study Type	Efficacy
Pertaining to	Infectious bovine rhinothracheitis (IBR) virus
Study Purpose	Demonstrate a duration of immunity of at least 280 days against respiratory disease caused by IBR virus
Product Administration	One dose administered subcutaneously
Study Animals	20 vaccinated and 10 control calves, four to five months of age, seronegative to IBR
Challenge Description	IBR virus administered 280 days post-vaccination
Interval observed after challenge	Animals were observed daily for 14 days following challenge
Results	IBR disease was the efficacy variable. IBR disease was defined as whether an animal ever exhibited one of the following clinical signs: depression, mucopurulent nasal discharge, and/or increased respiratory effort and sounds. IBR disease: Controls: 10/10 (100%) Vaccinates: 0/20 (0%) See individual data attached.
USDA Approval Date	March 19, 2010

IBR Disease by Treatment, Day and Animal

Controls

Animal	Day																
	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294
39	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
42	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
43	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No
54	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
56	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
61	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
62	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	No
63	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No
65	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
68	No	No	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No

Vaccinates

Animal	Day																
	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294
37	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
41	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
44	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
46	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
47	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
48	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
49	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
50	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
51	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
52	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
53	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
55	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
57	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
58	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
59	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
60	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
64	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
67	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
71	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
72	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Study Type	Efficacy
Pertaining to	*Mannheimia haemolytica*
Study Purpose	To demonstrate effectiveness against *Mannheimia haemolytica* at 9 weeks post vaccination
Product Administration	One dose administered subcutaneously
Study Animals	29 vaccinated and 28 control calves, two months of age
Challenge Description	*M. haemolytica* administered at 9 weeks post-vaccination.
Interval observed after challenge	Animals were observed daily for six days following challenge.
Results	Mortality was evaluated. Mortality: Controls: 26/28 (93%) Vaccinates: 17/29 (59%) See individual data attached.
USDA Approval Date	September 19, 2019

Mortality by Treatment and Animal

Controls

Animal	Mortality (prior to 6 days post-challenge)
3678	Yes
3685	Yes
3688	Yes
3689	Yes
3698	Yes
3709	Yes
3713	Yes
3714	Yes
3718	Yes
3721	Yes
3724	Yes
3730	Yes
3732	Yes
3734	Yes
3735	Yes
3736	Yes
3737	Yes
3741	No
3754	Yes
3755	Yes
3757	Yes
3758	Yes
3760	Yes
3762	Yes
3764	Yes
3765	Yes
3766	Yes
3768	No

Vaccinates

Animal	Mortality (prior to 6 days post-challenge)
3673	No
3690	No
3692	Yes
3695	No
3696	Yes
3699	Yes
3701	No
3703	No
3705	Yes
3706	No
3707	Yes
3708	Yes
3710	Yes
3711	Yes
3712	Yes
3715	Yes
3716	Yes
3717	Yes
3719	No
3722	No
3728	Yes
3738	Yes
3740	No
3742	Yes
3748	Yes
3749	No
3752	Yes
3753	No
3756	No

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate an onset of immunity of 7 days against respiratory disease caused by M. haemolytica</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>25 vaccinated and 25 control calves, six months of age</td></tr>
<tr><td>Challenge Description</td><td>M. haemolytica administered 7 days post-vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for six days following challenge</td></tr>
<tr><td>Results</td><td>Lung lesion (percent) was the efficacy variable.

Summary of lung lesions (percent):

<table>
<tr><th></th><th>Minimum</th><th>25th Percentile</th><th>Median</th><th>75th Percentile</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>6.3</td><td>12.8</td><td>18.1</td><td>27.3</td><td>53.6</td></tr>
<tr><td>Vaccinates</td><td>1.2</td><td>8.2</td><td>11.1</td><td>16.9</td><td>53.5</td></tr>
</table>

See individual data attached.</td></tr>
<tr><td>USDA Approval Date</td><td>September 26, 2016</td></tr>
</table>

Lung Lesions (Percent) by Treatment and Animal

Controls

Animal	Lung Lesions (%)
4819	22.61
4836	51.40
4838	17.91
4852	49.85
4853	44.25
4859	17.29
4862	18.09
4864	13.66
4867	17.38
4868	8.88
4872	6.69
4878	15.94
4879	12.84
4880	23.96
4883	33.70
4895	22.40
4897	27.30
4912	11.24
4918	22.08
4919	53.56
4925	46.19
4933	12.63
4936	25.00
4940	6.31
4945	7.60

Vaccinates

Animal	Lung Lesions (%)
4820	9.60
4821	18.96
4822	7.60
4824	7.83
4825	8.23
4829	25.37
4833	18.04
4837	9.34
4840	16.89
4842	5.66
4843	11.84
4845	9.13
4848	1.48
4860	48.87
4863	23.75
4869	53.50
4870	13.53
4874	11.08
4877	11.27
4881	11.19
4893	9.75
4900	1.21
4910	11.06
4913	15.52
4929	2.47

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against respiratory disease caused by M. haemolytica</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>20 vaccinated and 19 control calves, six months of age</td></tr>
<tr><td>Challenge Description</td><td>M. haemolytica administered 21 days post-vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for six days following challenge then lung lesions were evaluated</td></tr>
<tr><td>Results</td><td>Lung lesions (%) and mortality were efficacy variables.

Lung lesions:
<table>
<tr><th></th><th>Minimum</th><th>25th Percentile</th><th>Median</th><th>75th Percentile</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>8.7</td><td>23.3</td><td>41.5</td><td>47.4</td><td>55.2</td></tr>
<tr><td>Vaccinates</td><td>1.1</td><td>6.1</td><td>13.8</td><td>19.0</td><td>59.1</td></tr>
</table>
Mortality:
Controls: 9/19 (47.4%)
Vaccinates: 1/20 (5%)

See individual data attached.</td></tr>
<tr><td>USDA Approval Date</td><td>January 18, 2012</td></tr>
</table>

Lung Lesions and Mortality by Treatment and Animal

Controls

Animal	Lung Lesions (%)	Mortality (prior to 6 days post-challenge)
2024	46.5	No
2026	55.2	Yes
2037	44.8	Yes
2045	38.86	No
2046	26.28	No
2050	41.23	Yes
2052	17.31	No
2061	46.37	No
2065	18.55	No
2066	9.25	No
2085	48.7	Yes
2098	26.9	Yes
2108	48.25	Yes
2111	20.29	No
2117	41.47	Yes
2120	54.25	Yes
2123	46.5	Yes
2125	8.71	No
2128	49.82	No

Vaccinates

Animal	Lung Lesions (%)	Mortality (prior to 6 days post-challenge)
2023	16.71	No
2028	59.06	Yes
2031	11.84	No
2039	8.88	No
2040	16.25	No
2042	3.27	No
2051	19.9	No
2059	18.13	No
2072	15.05	No
2082	22.72	No
2084	1.26	No
2090	1.11	No
2091	1.54	No
2093	21.1	No
2106	11.83	No
2107	12.61	No
2116	17.75	No
2124	11.61	No
2127	2.4	No
2132	28.35	No

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Parainfluenza 3 (PI3) virus</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against respiratory disease caused by PI3 virus</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>17 vaccinated and 17 control calves, eight to ten months of age, seronegative to PI3</td></tr>
<tr><td>Challenge Description</td><td>PI3 virus administered 28 days post-vaccination (Study Day 28)</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for 14 days following challenge (Study Day 29-42).</td></tr>
<tr><td>Results</td><td>Duration of virus shedding (days) was the efficacy variable.

Summary of duration of virus shedding:

<table>
<tr><td></td><td>Minimum</td><td>25th Percentile</td><td>Median</td><td>75th Percentile</td><td>Maximum</td></tr>
<tr><td>Controls</td><td>7</td><td>7</td><td>9</td><td>10</td><td>12</td></tr>
<tr><td>Vaccinates</td><td>5</td><td>5</td><td>6</td><td>6</td><td>7</td></tr>
</table>

See individual data attached.</td></tr>
<tr><td>USDA Approval Date</td><td>March 06, 2013</td></tr>
</table>

Virus Shedding by Treatment, Day, and Animal

Controls

Animal	Study Day														
	27	29	30	31	32	33	34	35	36	37	38	39	40	41	42
4605	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
4613	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4615	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
4618	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
4622	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4651	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
4652	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4653	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
4661	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
4677	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4685	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4692	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
4694	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No
4703	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
4707	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No
4717	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
4718	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	No	No

Vaccinates

Animal	Study Day														
	27	29	30	31	32	33	34	35	36	37	38	39	40	41	42
4600	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4601	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4614	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4619	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4629	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4647	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4650	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No
4654	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4655	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4657	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	*				
4663	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4674	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4696	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4700	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4704	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
4711	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
4714	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No

*Animal was removed from study on Day 37 due to causes unrelated to vaccine administration.

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncitial Virus (BRSV)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BRSV
Product Administration	One dose administered subcutaneously
Study Animals	16 vaccinated and 16 control calves, two months of age
Challenge Description	BRSV administered 21 days post-vaccination
Interval observed after challenge	Animals were observed daily for eight days following challenge (Study Day 22-Study Day 29)
Results	Mortality was the efficacy variable. Mortality: Controls: 13/16 (81.3%) Vaccines 0/16 (0%) See individual data attached.
USDA Approval Date	March 05, 2013

Mortality by Treatment and Animal

Controls

Animal				
	SD 26	SD 27	SD 28	Summary
02		√		Yes
05			√	Yes
06		√		Yes
07		√		Yes
11				No
14		√		No
19		√		Yes
20		√		Yes
22		√		Yes
23		√		Yes
24		√		Yes
27		√		Yes
28		√		Yes
29		√		Yes
31				No
34	√			Yes

<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>Demonstrate safety under field conditions in calves and pregnant animals</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>1,486 vaccinated and 738 control animals, including animals in all three trimesters of pregnancy, in five geographical regions</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for four hours after vaccination and daily for 28 days. Pregnant animals were observed daily for abortions. Visual assessments of injection site reactions were completed on days 7, 14, 21, and 28 post-vaccination.</td></tr>
<tr><td>Results</td><td><u>Number of Animals with Adverse Events</u>
<table>
<tr><th></th><th></th><th>Normal</th><th>Abortion</th><th>Abdominal Pain</th><th>Abnormal Breathing</th><th>Injection Site Pyoderma</th><th>Lameness</th><th>Panting</th><th>Other</th></tr>
<tr><td rowspan="5">Controls</td><td>Pre-Weaned Calves</td><td>172</td><td>0</td><td>1</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Post-Weaned Calves</td><td>182</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>1st Trimester</td><td>109</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>2nd Trimester</td><td>131</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>3rd Trimester</td><td>138</td><td>2</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td rowspan="5">Vaccinates</td><td>Pre-Weaned Calves</td><td>352</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>Post-Weaned Calves</td><td>358</td><td>0</td><td>1</td><td>6</td><td>1</td><td>2</td><td>0</td><td>0</td></tr>
<tr><td>1st Trimester</td><td>220</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>2nd Trimester</td><td>264</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>3rd Trimester</td><td>279</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
</table>
<u>Number of Animals with Injection Site Reactions</u>
<table>
<tr><th></th><th>Controls</th><th>Vaccinates</th></tr>
<tr><td>Pre-Weaned Calves</td><td>0</td><td>0</td></tr>
<tr><td>Post-Weaned Calves</td><td>0</td><td>2</td></tr>
<tr><td>1st Trimester</td><td>0</td><td>0</td></tr>
<tr><td>2nd Trimester</td><td>1</td><td>19</td></tr>
<tr><td>3rd Trimester</td><td>0</td><td>2</td></tr>
</table>
Injection site reactions were < 5cm except for one post-weaned calf had an injection site reaction > 5cm. All reactions resolved within 33 days of vaccination.</td></tr>
<tr><td>USDA Approval Date</td><td>April 16, 2013</td></tr>
</table>