



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1171.24
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3 Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovi-Shield Gold 4 - No distributor specified
Date of Compilation Summary	August 15, 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

Study Type	Efficacy									
Pertaining to	Bovine Viral Diarrhea Virus, type 1 (BVDV 1)									
Study Purpose	Demonstrate at least 9-month duration of immunity against respiratory disease caused by BVDV 1									
Product Administration	One dose administered subcutaneously (SC)									
Study Animals	20 vaccinates and 10 control calves, 5 months of age and seronegative for BVDV1 and BVDV 2 (serum neutralizing antibody titer <1:2)									
Challenge Description	BVDV 1 virus (non-cytopathic type 1b strain New York-1) administered 279 days following vaccination									
Interval observed after challenge	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.									
Results	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><td></td><td>Viremia</td><td>Leukopenia</td></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.		Viremia	Leukopenia	Controls	9/10 (90%)	7/10 (70%)	Vaccinates	0/20 (0%)	0/20 (0%)
	Viremia	Leukopenia								
Controls	9/10 (90%)	7/10 (70%)								
Vaccinates	0/20 (0%)	0/20 (0%)								
USDA Approval Date	01/26/2011									

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/ μ L)												
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

Study Type	Efficacy																													
Pertaining to	Bovine viral diarrhea virus type 2 (BVDV2)																													
Study Purpose	Demonstrate efficacy against respiratory disease caused by BVDV2 in calves.																													
Product Administration	One dose was administered intramuscularly.																													
Study Animals	Twenty-nine, 3-4-month-old beef calves, 19 vaccinates and 10 controls. Seronegative (<1:2) to BVDV1 and BVDV2 at vaccination.																													
Challenge Description	BVDV2a Strain 24515 (non-cytopathic) administered 35 days following vaccination.																													
Interval observed after challenge	Animals were clinically observed for 15 days following challenge. Blood samples were collected daily for 14 and 15 days for virus isolation, and white blood cell counts respectively.																													
Results	Viremia was defined as at least one occasion where virus was isolated post-challenge. Leukopenia was defined as $\geq 40\%$ drop from baseline measurements at any time post-challenge. Duration of clinical signs, including nasal discharge, abnormal respiration, lethargy, gauntness, ocular discharge, hypersalivation, diarrhea, dehydration, lameness and/or reluctance to move, was evaluated. <u>Leukopenia and Viremia Results:</u> <table><tr><th rowspan="2">Treatment</th><th colspan="2">Ever Present</th></tr><tr><th>Leukopenia</th><th>Viremia</th></tr><tr><td>Controls</td><td>10/10 (100%)</td><td>10/10 (100%)</td></tr><tr><td>Vaccinates</td><td>0/19 (0%)</td><td>2/19 (10.5%)</td></tr></table> <u>Duration of clinical signs:</u> <table><tr><th>Group</th><th>Min.</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max.</th></tr><tr><td>Controls</td><td>0</td><td>6</td><td>9</td><td>13</td><td>16</td></tr><tr><td>Vaccinates</td><td>0</td><td>0</td><td>1</td><td>4</td><td>12</td></tr></table> See attached pages for individual animal data.	Treatment	Ever Present		Leukopenia	Viremia	Controls	10/10 (100%)	10/10 (100%)	Vaccinates	0/19 (0%)	2/19 (10.5%)	Group	Min.	Q1	Median	Q3	Max.	Controls	0	6	9	13	16	Vaccinates	0	0	1	4	12
Treatment	Ever Present																													
	Leukopenia	Viremia																												
Controls	10/10 (100%)	10/10 (100%)																												
Vaccinates	0/19 (0%)	2/19 (10.5%)																												
Group	Min.	Q1	Median	Q3	Max.																									
Controls	0	6	9	13	16																									
Vaccinates	0	0	1	4	12																									
USDA Approval Date	7/17/2008																													

Clinical Disease:

Treatment	ID	Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 43	Day 44	Day 45	Day 46	Day 47	Day 48	Day 49	Day 50	Day 51
Controls	14	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	0
	16	0	0	1	1	1	1	0	0	1	1	2	2	2	2	2	2
	21	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	27	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0
	30	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0	0
	35	0	0	0	1	1	0	1	1	1	1	1	2	2	2	2	2
	36	0	0	0	0	0	0	0	1	1	1	1	1	0	0	1	0
	37	0	0	0	0	0	0	1	1	1	0	1	2	2	2	2	2
	40	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	54	1	0	0	0	1	1	0	0	1	1	1	2	2	2	2	2
Vaccinates	02	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	03	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
	04	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
	06	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	07	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	13	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	25	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
	28	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	32	1	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
	34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	39	0	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0
	41	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0
	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	46	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	53	0	0	0	0	1	0	0	0	0	1	1	1	0	0	0	0

0= Normal animal: no clinical signs. 1= Nonspecific clinical signs: clinical signs are not specific for acute BVDV infection. Clinical signs may include nasal discharge, abnormal respiration and mild lethargy. 2= Acute BVDV clinical disease: Clinical signs are moderate in degree and specific for acute BVDV infection. Clinical signs may include nasal discharge, abnormal respiration, lethargy, gauntness, ocular discharge, hypersalivation, diarrhea, dehydration, lameness and/or reluctance to move.

Leukopenia:

Treatment	ID	Leukopenia (yes / no)														
		Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 43	Day 44	Day 45	Day 46	Day 47	Day 48	Day 49	Day 50
Controls	14	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
	16	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	21	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
	27	N	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N
	30	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	N
	35	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	N
	36	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
	37	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	40	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N
Vaccinates	54	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	02	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	03	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	04	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	05	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	06	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	07	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	13	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	25	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	28	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
	32	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	34	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	39	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
	43	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	44	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	45	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	46	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	53	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Y= Yes for a 40% or greater drop in white blood cell count. N= No for a 40% or greater drop in white blood cell count.

Trt	ID	Individual Animal White Blood Cell Counts (x 1000/uL)																	
		Day 33	Day 34	Day 35	Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 43	Day 44	Day 45	Day 46	Day 47	Day 48	Day 49	Day 50
Ctrls	14	12.8	12.6	8.7	7.0	7.4	8.5	7.3	7.1	7.9	7.6	6.9	6.7	5.4	5.7	5.2	4.0	3.6	5.0
	16	16.5	16.3	16.0	15.7	14.1	9.1	7.8	6.4	5.8	5.4	4.8	4.6	4.2	4.1	4.2	4.2	3.9	4.2
	21	12.2	12.3	10.8	11.1	10.5	7.7	6.8	5.4	5.3	4.7	5.1	6.3	6.8	5.2	5.4	5.6	5.5	7.1
	27	14.5	14.2	15.6	16.0	13.2	6.1	6.0	6.3	5.4	5.9	5.6	8.5	9.1	7.7	6.4	7.3	8.4	9.7
	30	13.4	11.8	13.0	12.1	11.9	8.1	8.3	8.5	8.4	8.6	10.1	9.3	11.7	8.2	7.7	6.9	7.6	9.0
	35	10.2	11.4	10.5	9.4	8.7	9.2	8.6	7.1	7.4	6.4	5.7	4.0	4.2	4.7	5.3	4.6	4.3	6.9
	36	16.5	16.7	18.4	18.6	17.5	8.0	9.4	8.9	7.8	7.4	6.5	6.1	9.4	8.4	10.1	8.9	10.3	13.7
	37	14.4	14.7	15.1	13.3	11.7	6.6	6.7	5.1	5.9	6.4	4.9	4.7	3.9	3.5	3.6	3.2	2.8	3.2
	40	14.7	13.5	14.7	12.6	10.9	6.4	7.3	5.6	5.0	5.8	5.8	5.8	7.9	7.5	8.6	9.8	8.6	9.8
54	13.1	12.5	13.9	13.4	12.3	7.5	7.5	7.1	6.0	5.4	4.4	4.3	3.4	2.0	1.5	1.9	1.6	2.3	
Vactes	02	20.0	20.5	20.2	18.8	19.1	19.1	17.5	17.1	15.6	14.0	16.0	14.9	13.8	15.8	16.1	17.1	15.4	17.2
	03	12.2	10.1	9.1	8.0	9.2	9.6	7.5	7.3	6.7	8.2	11.1	14.7	17.4	12.3	11.7	9.7	9.0	10.1
	04	9.8	9.4	9.1	9.8	10.4	11.1	9.2	8.8	9.6	10.1	9.2	10.6	11.0	11.7	10.8	11.1	12.0	13.6
	05	13.9	14.3	14.0	13.2	13.8	11.0	9.7	9.3	9.3	9.0	11.0	11.7	11.8	10.1	11.0	10.5	10.1	11.6
	06	11.1	11.9	10.7	10.6	11.4	10.0	7.4	7.3	8.1	8.7	11.1	8.7	8.4	8.2	10.5	9.7	8.9	9.3
	07	12.7	13.5	13.1	11.4	12.3	12.1	12.1	11.5	10.7	10.8	11.4	11.1	10.9	10.8	11.1	11.3	10.6	11.0
	13	12.5	13.6	14.1	12.4	12.1	12.0	12.0	11.7	12.3	12.0	12.6	13.8	13.5	14.3	15.8	15.3	14.2	16.9
	25	19.7	18.3	16.4	14.4	14.9	16.2	15.4	16.1	16.6	14.8	15.6	17.0	16.5	16.7	15.3	16.8	15.5	17.1
	28	13.4	13.3	13.1	13.5	12.5	12.0	11.9	11.0	12.0	11.8	11.0	10.6	10.2	10.8	11.6	11.7	9.9	11.3
	29	13.8	13.1	13.0	12.2	12.2	12.9	11.8	12.0	11.3	11.2	10.9	11.6	12.4	12.1	13.0	12.9	11.4	12.0
	32	12.5	12.4	12.6	12.9	10.8	10.5	9.3	9.3	9.1	9.9	9.8	11.9	10.8	11.0	11.5	12.4	10.7	11.3
	34	11.7	9.5	10.5	11.7	12.2	11.5	10.3	11.4	9.3	8.8	9.4	8.9	9.0	9.1	9.9	10.6	11.8	12.3
	39	17.2	17.7	15.8	14.7	15.1	14.8	14.3	14.0	14.8	13.3	12.4	12.2	11.7	11.2	11.4	11.1	10.8	11.9
	41	10.7	11.1	11.6	12.3	11.1	11.8	11.3	10.1	11.3	11.5	12.3	12.4	12.0	11.4	11.7	12.4	11.6	12.7
	43	13.4	13.3	12.8	14.3	13.1	13.8	13.0	12.5	10.5	11.1	10.5	12.7	12.8	14.8	14.0	15.0	14.0	13.2
	44	12.3	11.3	11.3	9.9	10.3	10.0	7.5	8.7	7.6	7.5	8.7	8.8	9.4	9.7	10.2	10.3	10.9	11.6
	45	12.9	13.1	12.0	12.9	9.7	10.3	11.2	11.4	10.1	13.1	12.5	13.5	14.3	15.1	13.7	14.1	14.0	14.0
	46	14.1	15.9	12.8	12.5	11.8	13.3	12.1	13.3	13.4	15.6	16.3	14.1	13.2	13.0	12.3	13.5	11.7	11.1
	53	13.5	13.6	13.8	9.9	8.2	10.5	9.5	11.9	8.7	11.5	12.3	11.9	16.5	12.5	12.3	11.3	12.6	13.6

Trt: Treatment; Ctrls: Controls; Vactes: Vaccinates

Days 33, 34 and 35 were used to set the baseline for WBC counts

Viremia:

Treatment	ID	Virus Isolation (yes / no)													
		Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 43	Day 44	Day 45	Day 46	Day 47	Day 48	Day 49
Controls	14	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	16	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
	21	N	N	N	N	Y	Y	Y	Y	Y	Y	N	N	N	N
	27	N	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N	N
	30	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	N
	35	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
	36	N	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	N	N
	37	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N
	40	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	N
Vaccinates	54	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
	02	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	03	N	N	N	N	N	Y	N	N	N	N	N	N	N	N
	04	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	05	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	06	N	N	N	N	N	N	N	N	N	N	Y	N	N	N
	07	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	13	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	25	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	28	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
	32	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	34	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	39	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
	43	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	44	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	45	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	46	N	-*	N	N	N	N	N	N	N	N	N	N	N	N
	53	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Y= Yes for virus isolation from sample. N= No for virus isolation from sample. * Virus isolation data was not obtained due to loss of sample and it was excluded from data analysis.

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus, type 2 (BVDV2)
Study Purpose	Demonstrate at least 9-month duration of immunity against respiratory disease caused by BVDV2
Product Administration	One dose administered subcutaneously (SC)
Study Animals	20 vaccinates and 10 control calves, 4 to 5 months of age and seronegative for BVDV1 and BVDV2 (serum neutralizing antibody titer <1:2)
Challenge Description	BVDV2 virus (non-cytopathic type 2a strain 24515) administered 280 days following vaccination (Study Day 280)
Interval observed after challenge	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.
Results	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).
	See attached pages for individual animal data.
USDA Approval Date	01/26/2011

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/ μ l)															
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	Herpesvirus, bovine (IBR)
Study Purpose	Demonstrate efficacy against respiratory disease caused by infectious bovine rhinotracheitis
Product Administration	
Study Animals	Bovine
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	01/08/2001

Study Type	Efficacy
Pertaining to	Infectious bovine rhinotracheitis (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	Herpesvirus, bovine [Infectious Bovine Rhinotracheitis (IBR) Virus]
Study Purpose	Demonstrate efficacy against respiratory disease caused by infectious bovine rhinotracheitis
Product Administration	One dose administered intramuscularly (IM) or subcutaneously (SC)
Study Animals	20 IM vaccinates, 20 SC vaccinates, and 10 control calves, 6–8 months of age and seronegative to IBR (serum neutralizing antibody titer < 1:2). The study was conducted per 9 CFR 113.310.
Challenge Description	IBR virus administered on day 35
Interval observed after challenge	Animals were observed daily for 14 days
Results	Animals were considered to have IBR disease if a clinical sign was observed/detected on at least one day post-challenge to include depression, nasal discharge, rectal temperature , or increased respiratory effort. Number of animals affected (IBR disease): Controls: 10/10 (100%) IM vaccinates: 4/20 (20%) SC vaccinates: 2/20 (10%)
USDA Approval Date	01/23/2008

IBR Disease: Depression

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2123	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	
	2145	0	0	0	0	0	1	1	1	1	0	1	1	0	0	0	
	2148	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	
	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2161	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	
	2171	0	0	0	0	0	1	0	1	1	1	1	0	0	0	0	
	2178	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	
	2197	0	0	0	0	0	0	1	1	1	1	1	1	0	1	0	
2200	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0		
IM Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
SC Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = Normal. Alert, active, stands, moves and responds to stimuli quickly and steadily, shows continuous interest in surroundings.

1 = Mild. Tends to lie down frequently, lethargic and somnolent, stands, moves and responds to stimuli reluctantly and unsteadily, holds head low, staggers, shows little interest in surroundings.

2 = Severe. Recumbent or shows little or no response to stimuli or stands/moves with difficulty.

IBR Disease: Nasal Discharge

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
	2123	0	0	0	0	0	1	0	0	0	1	0	1	1	0	0	
	2145	0	0	0	1	1	1	1	1	1	1	0	1	0	1	0	
	2148	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	
	2153	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	
	2161	0	0	0	0	0	1	1	1	1	1	1	0	1	1	0	
	2171	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
	2178	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0	
	2197	0	0	0	0	0	1	0	1	1	1	1	1	1	0	1	
2200	0	0	0	0	0	0	1	1	1	1	1	0	1	0	0		
SC Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
IM Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = No discharge/small amount of discharge (approx. 1 mL or less) of clear, mucoid or whitish discharge.

1 = Mild. Notable amount (approx. 2–3 mL or more) of clear mucoid discharge streaked with mucopurulent discharge running down the nostrils.

2 = Severe. Notable amount (approx. 2–3 mL or more) of mucopurulent discharge running down the nostrils.

IBR Disease: Respiratory Effort

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2148	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2161	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
	2171	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
	2178	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2197	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
SC Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
IM Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = Normal. Respirations are shallow and mostly thoracic (difficult to see at a distance of approximately 10 feet).

1 = Mild. Respirations are rapid, labored and mostly abdominal.

2 = Severe. Respirations are very labored or animal grunts during breathing.

Rectal Temperatures (°C)

Treatment Group	Animal Id	Study Day														
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
Controls	2119	39.1	38.9	38.9	40.9	40.4	40.4	40.5	39.9	39.5	39	38.7	38.5	38.7	38.7	38.7
	2123	39.2	39.1	40.4	41.6	41.5	41.4	40.4	40.5	40.7	40.6	39.9	39	38.9	38.8	38.6
	2145	39.4	39	39.2	41.7	41.3	41.1	40.6	39.7	40	40	38.9	38.8	39.2	39.2	39
	2148	39.1	39.3	39.3	40.8	41.3	40.4	40.4	40	39.5	39.1	39	39.1	38.7	38.7	38.6
	2153	39.4	39.2	39.3	39.9	40.7	40.4	40	39	39.6	39.2	39.2	38.9	39.3	39.3	39.1
	2161	39.2	39.6	41	42.3	41.7	41.5	40.9	40.4	40.1	39.9	39.3	39.3	38.9	39	38.7
	2171	39.3	39.2	39.3	41.8	40.7	40.9	40.7	40.6	40.6	40.6	39.6	39.3	38.8	39.2	38.6
	2178	39.2	39.2	38.8	41.2	41.7	41.2	41.1	40.7	40.1	39.4	39.2	39.1	38.9	39.1	39.1
	2197	39.1	39	39.4	41.6	41.4	40.4	40.4	40.5	39.6	39.7	39	39.1	38.6	38.9	38.8
	2200	39.5	39.3	39.3	41.1	40.6	40.9	40.3	40.2	39.7	39.8	38.9	39.1	38.8	38.9	39.1
SC Vaccinates	2122	39.3	39.1	39.3	39.2	39.5	39	39.1	39	39	38.9	39.2	38.7	39.1	39.1	39.2
	2126	39	38.8	38.9	38.9	38.7	38.8	39	38.6	38.9	38.9	38.8	38.9	38.6	38.7	38.7
	2127	39.4	39.3	39	39.3	39.1	39.1	39.6	39.1	39.5	39.2	39.2	39.3	39.4	38.9	38.9
	2131	39.1	39	38.8	39.2	39	38.8	38.7	39.7	39.4	38.7	38.8	38.7	39.1	38.8	39.1
	2140	39.1	38.9	39	38.6	38.7	38.8	38.8	38.7	38.8	38.7	38.6	38.7	38.7	39.1	38.8
	2150	38.9	39	38.9	38.8	39.1	39	38.7	38.6	38.8	38.9	38.8	38.7	38.9	38.9	38.9
	2151	39.3	39.2	39	39	38.9	38.7	38.9	38.9	38.8	38.8	38.7	38.8	38.8	38.9	38.5
	2155	39.3	39.2	38.7	39	39.2	38.8	39	38.8	38.9	39.1	39	39.1	39	38.8	38.9
	2163	39.2	39	38.9	38.9	38.9	39	39.3	38.7	38.6	38.8	38.9	39	38.7	39.1	39
	2164	39.2	39.3	39.3	39	39.5	39.4	39	39.3	39.1	39.2	39	39.3	38.8	38.7	38.9
	2168	38.7	38.9	38.7	39	39.1	39	38.7	38.9	39	38.8	38.8	38.7	39	38.7	39.2
	2174	39	38.9	38.9	40.4	40.5	40.3	38.9	38.8	38.7	38.9	38.9	39	38.8	38.6	38.8
	2176	39	38.8	39.1	39.3	38.8	39.1	38.8	38.8	39.1	38.9	39.1	38.8	38.7	38.6	39
	2181	38.9	39.2	38.7	38.8	39.2	39.4	39.2	39.3	38.9	39.1	38.8	38.7	39	38.8	39.1
	2183	38.9	38.9	38.8	39	39.1	39	38.8	38.7	38.8	38.8	39	39.1	38.5	39	39.1
	2185	39.2	39.6	39.5	40.5	40.1	39.9	39.1	39.3	39.1	39.1	39.2	39.1	39	38.8	39.3
	2188	39.4	39.5	39.6	39.4	39.1	39.4	39.4	39.4	39.2	39.4	39.4	39	39.3	39.1	39.2
	2189	38.8	38.8	39	38.6	39.1	38.7	38.7	38.8	39	38.9	39	39.1	38.9	39	38.7
	2198	39.3	39.2	38.9	39.1	38.8	39	39.1	39	38.8	38.9	38.9	39	38.8	38.8	38.7
	2199	39.1	39.1	39	38.9	39.2	38.9	38.9	39.1	39.3	39	39	39	38.8	38.8	38.8
IM Vaccinates	2121	38.9	39.1	38.9	38.7	39	39	38.8	38.9	39.2	38.7	39.1	38	38.7	38.9	38.9
	2124	39	38.9	39.1	39.2	39	39	39.1	38.9	39.1	38.8	39.2	38.9	39	38.7	38.9
	2125	39	38.8	38.8	38.8	38.9	38.8	38.8	38.9	38.9	38.9	39.1	39.1	38.9	39	39.1
	2128	39.2	39	39.1	38.9	38.9	39.1	38.7	39.2	39.1	38.9	38.9	38.9	38.9	38.9	38.8
	2129	39	39.2	39.2	39.3	39.3	39.2	38.9	39.4	39.1	39.1	39.4	38.7	38.9	38.8	39.1
	2130	39	39.2	39	39.3	38.9	38.9	38.9	39.1	39.2	39	39	39.1	38.7	38.6	38.8
	2132	39.6	39.9	39.4	39.2	39.5	39.4	39.2	39	39.2	39	39.3	39.1	39.2	39	39.1
	2133	38.9	38.8	38.8	38.9	38.8	38.8	38.9	38.7	38.8	38.6	39.1	38.8	38.8	38.6	38.7
	2139	39	39.2	39.4	38.7	38.9	38.8	39	39.1	38.7	38.9	38.7	38.9	38.9	39	38.8
	2147	39	39	38.9	38.8	39	38.9	38.8	38.8	38.7	38.7	38.6	38.8	39.2	38.7	38.8
	2149	39.2	39.2	38.9	39.1	39	38.8	38.8	38.9	38.7	38.7	39.2	38.7	38.7	38.7	38.9
	2156	39	38.9	38.9	39.1	39.2	39.3	39.2	38.8	38.6	38.8	38.9	38.7	38.9	38.8	39.1
	2162	38.9	39.3	39.3	38.9	39.2	39.4	38.9	39	39	38.9	39.4	38.9	38.8	38.7	39.1
	2166	39.2	39.1	38.9	39.3	39.1	39.1	38.8	39	38.9	39.2	39.3	39.1	38.9	38.9	38.8
	2167	38.9	38.6	38.7	38.7	38.7	38.7	38.9	38.6	38.7	38.8	38.6	38.8	38.7	38.9	38.7
	2169	39.3	39.1	38.9	39	39	39.3	38.9	39	39.2	38.9	39.1	39.1	38.8	39	39
	2172	39.9	39	38.8	39.2	38.8	38.9	39.1	39.1	38.9	38.9	38.9	39	38.9	38.8	38.6
	2175	39.1	38.8	38.6	38.6	38.9	39	38.7	38.7	38.8	38.6	38.9	39	38.7	38.9	38.6
	2177	39.1	39.5	39.3	39.3	39	39	38.9	39.1	38.7	39	39.6	38.9	39.1	38.9	39
	2193	39	39.3	39	39.1	39.3	38.9	38.8	39.5	39.1	39	38.8	38.8	38.6	38.7	39

IBR Serum Neutralization

Treatment Group	Animal Id	Study Day			
		0	27	34	49
Controls	2119	<2	<2	<2	38
	2123	<2	<2	<2	23
	2145	<2	<2	<2	76
	2148	<2	<2	<2	54
	2153	<2	<2	<2	38
	2161	<2	<2	<2	54
	2171	<2	<2	<2	76
	2178	<2	<2	<2	27
	2197	<2	<2	<2	76
	2200	<2	<2	<2	76
SC Vaccinates	2122	<2	11	16	431
	2126	<2	32	23	215
	2127	<2	16	16	215
	2131	<2	29	27	128
	2140	<2	27	23	152
	2150	<2	19	19	181
	2151	<2	23	23	304
	2155	<2	38	45	45
	2163	<2	14	16	215
	2164	<2	19	19	152
	2168	<2	36	23	181
	2174	<2	6	4	362
	2176	<2	13	19	609
	2181	<2	23	23	304
	2183	<2	9	10	304
	2185	<2	10	5	512
	2188	<2	13	11	362
	2189	<2	13	13	215
	2198	<2	32	32	181
	2199	<2	18	27	362
IM Vaccinates	2121	<2	23	27	128
	2124	<2	16	16	256
	2125	<2	16	19	45
	2128	<2	19	19	362
	2129	<2	16	16	54
	2130	<2	27	23	256
	2132	<2	13	16	304
	2133	<2	38	45	304
	2139	<2	32	45	76
	2147	<2	13	16	256
	2149	<2	45	38	181
	2156	<2	13	13	91
	2162	<2	13	10	609
	2166	<2	11	13	431
	2167	<2	27	23	108
	2169	<2	11	13	152
	2172	<2	19	23	152
	2175	<2	13	16	152
	2177	<2	6	6	256
	2193	<2	45	45	181

Titers are expressed as the greatest neutralizing dilution.

Study Type	Efficacy
Pertaining to	Herpesvirus, bovine [Infectious Bovine Rhinotracheitis (IBR) Virus]
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR
Product Administration	One dose administered intramuscularly (IM) or subcutaneously (SC)
Study Animals	20 IM vaccinates, 20 SC vaccinates, and 10 control calves, 6–8 months of age and seronegative to IBR (serum neutralizing antibody titer < 1:2). The study was conducted per 9 CFR 113.310.
Challenge Description	IBR virus administered on day 35
Interval observed after challenge	Animals were observed daily for 14 days
Results	Animals were considered to have IBR disease if a clinical sign was observed/detected on at least one day post-challenge to include depression, nasal discharge, rectal temperature , or increased respiratory effort. Number of animals affected (IBR disease): Controls: 10/10 (100%) IM vaccinates: 4/20 (20%) SC vaccinates: 2/20 (10%)
USDA Approval Date	01/23/2008

IBR Disease: Depression

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2123	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	
	2145	0	0	0	0	0	1	1	1	1	0	1	1	0	0	0	
	2148	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	
	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2161	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	
	2171	0	0	0	0	0	1	0	1	1	1	1	0	0	0	0	
	2178	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	
	2197	0	0	0	0	0	0	1	1	1	1	1	1	0	1	0	
2200	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0		
IM Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
SC Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = Normal. Alert, active, stands, moves and responds to stimuli quickly and steadily, shows continuous interest in surroundings.

1 = Mild. Tends to lie down frequently, lethargic and somnolent, stands, moves and responds to stimuli reluctantly and unsteadily, holds head low, staggers, shows little interest in surroundings.

2 = Severe. Recumbent or shows little or no response to stimuli or stands/moves with difficulty.

IBR Disease: Nasal Discharge

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
	2123	0	0	0	0	0	1	0	0	0	1	0	1	1	0	0	
	2145	0	0	0	1	1	1	1	1	1	1	0	1	0	1	0	
	2148	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	
	2153	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	
	2161	0	0	0	0	0	1	1	1	1	1	1	0	1	1	0	
	2171	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
	2178	0	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0
	2197	0	0	0	0	0	0	1	0	1	1	1	1	1	1	0	1
2200	0	0	0	0	0	0	0	1	1	1	1	1	0	1	0	0	
SC Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
IM Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = No discharge/small amount of discharge (approx. 1 mL or less) of clear, mucoid or whitish discharge.

1 = Mild. Notable amount (approx. 2–3 mL or more) of clear mucoid discharge streaked with mucopurulent discharge running down the nostrils.

2 = Severe. Notable amount (approx. 2–3 mL or more) of mucopurulent discharge running down the nostrils.

IBR Disease: Respiratory Effort

Treatment Group	Animal Id	Study Day															
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	
Controls	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2148	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2161	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
	2171	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
	2178	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2197	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
SC Vaccinates	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
IM Vaccinates	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = Normal. Respirations are shallow and mostly thoracic (difficult to see at a distance of approximately 10 feet).

1 = Mild. Respirations are rapid, labored and mostly abdominal.

2 = Severe. Respirations are very labored or animal grunts during breathing.

Rectal Temperatures (°C)

Treatment Group	Animal Id	Study Day														
		35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
Controls	2119	39.1	38.9	38.9	40.9	40.4	40.4	40.5	39.9	39.5	39	38.7	38.5	38.7	38.7	38.7
	2123	39.2	39.1	40.4	41.6	41.5	41.4	40.4	40.5	40.7	40.6	39.9	39	38.9	38.8	38.6
	2145	39.4	39	39.2	41.7	41.3	41.1	40.6	39.7	40	40	38.9	38.8	39.2	39.2	39
	2148	39.1	39.3	39.3	40.8	41.3	40.4	40.4	40	39.5	39.1	39	39.1	38.7	38.7	38.6
	2153	39.4	39.2	39.3	39.9	40.7	40.4	40	39	39.6	39.2	39.2	38.9	39.3	39.3	39.1
	2161	39.2	39.6	41	42.3	41.7	41.5	40.9	40.4	40.1	39.9	39.3	39.3	38.9	39	38.7
	2171	39.3	39.2	39.3	41.8	40.7	40.9	40.7	40.6	40.6	40.6	39.6	39.3	38.8	39.2	38.6
	2178	39.2	39.2	38.8	41.2	41.7	41.2	41.1	40.7	40.1	39.4	39.2	39.1	38.9	39.1	39.1
	2197	39.1	39	39.4	41.6	41.4	40.4	40.4	40.5	39.6	39.7	39	39.1	38.6	38.9	38.8
2200	39.5	39.3	39.3	41.1	40.6	40.9	40.3	40.2	39.7	39.8	38.9	39.1	38.8	38.9	39.1	
SC Vaccinates	2122	39.3	39.1	39.3	39.2	39.5	39	39.1	39	39	38.9	39.2	38.7	39.1	39.1	39.2
	2126	39	38.8	38.9	38.9	38.7	38.8	39	38.6	38.9	38.9	38.8	38.9	38.6	38.7	38.7
	2127	39.4	39.3	39	39.3	39.1	39.1	39.6	39.1	39.5	39.2	39.2	39.3	39.4	38.9	38.9
	2131	39.1	39	38.8	39.2	39	38.8	38.7	39.7	39.4	38.7	38.8	38.7	39.1	38.8	39.1
	2140	39.1	38.9	39	38.6	38.7	38.8	38.8	38.7	38.8	38.7	38.6	38.7	38.7	39.1	38.8
	2150	38.9	39	38.9	38.8	39.1	39	38.7	38.6	38.8	38.9	38.8	38.7	38.9	38.9	38.9
	2151	39.3	39.2	39	39	38.9	38.7	38.9	38.9	38.8	38.8	38.7	38.8	38.8	38.9	38.5
	2155	39.3	39.2	38.7	39	39.2	38.8	39	38.8	38.9	39.1	39	39.1	39	38.8	38.9
	2163	39.2	39	38.9	38.9	38.9	39	39.3	38.7	38.6	38.8	38.9	39	38.7	39.1	39
	2164	39.2	39.3	39.3	39	39.5	39.4	39	39.3	39.1	39.2	39	39.3	38.8	38.7	38.9
	2168	38.7	38.9	38.7	39	39.1	39	38.7	38.9	39	38.8	38.8	38.7	39	38.7	39.2
	2174	39	38.9	38.9	40.4	40.5	40.3	38.9	38.8	38.7	38.9	38.9	39	38.8	38.6	38.8
	2176	39	38.8	39.1	39.3	38.8	39.1	38.8	38.8	39.1	38.9	39.1	38.8	38.7	38.6	39
	2181	38.9	39.2	38.7	38.8	39.2	39.4	39.2	39.3	38.9	39.1	38.8	38.7	39	38.8	39.1
	2183	38.9	38.9	38.8	39	39.1	39	38.8	38.7	38.8	38.8	39	39.1	38.5	39	39.1
	2185	39.2	39.6	39.5	40.5	40.1	39.9	39.1	39.3	39.1	39.1	39.2	39.1	39	38.8	39.3
	2188	39.4	39.5	39.6	39.4	39.1	39.4	39.4	39.4	39.2	39.4	39.4	39	39.3	39.1	39.2
	2189	38.8	38.8	39	38.6	39.1	38.7	38.7	38.8	39	38.9	39	39.1	38.9	39	38.7
	2198	39.3	39.2	38.9	39.1	38.8	39	39.1	39	38.8	38.9	38.9	39	38.8	38.8	38.7
	2199	39.1	39.1	39	38.9	39.2	38.9	38.9	39.1	39.3	39	39	39	38.8	38.8	38.8
IM Vaccinates	2121	38.9	39.1	38.9	38.7	39	39	38.8	38.9	39.2	38.7	39.1	38	38.7	38.9	38.9
	2124	39	38.9	39.1	39.2	39	39	39.1	38.9	39.1	38.8	39.2	38.9	39	38.7	38.9
	2125	39	38.8	38.8	38.8	38.9	38.8	38.8	38.9	38.9	38.9	39.1	39.1	38.9	39	39.1
	2128	39.2	39	39.1	38.9	38.9	39.1	38.7	39.2	39.1	38.9	38.9	38.9	38.9	38.9	38.8
	2129	39	39.2	39.2	39.3	39.3	39.2	38.9	39.4	39.1	39.1	39.4	38.7	38.9	38.8	39.1
	2130	39	39.2	39	39.3	38.9	38.9	38.9	39.1	39.2	39	39	39.1	38.7	38.6	38.8
	2132	39.6	39.9	39.4	39.2	39.5	39.4	39.2	39	39.2	39	39.3	39.1	39.2	39	39.1
	2133	38.9	38.8	38.8	38.9	38.8	38.8	38.9	38.7	38.8	38.6	39.1	38.8	38.8	38.6	38.7
	2139	39	39.2	39.4	38.7	38.9	38.8	39	39.1	38.7	38.9	38.7	38.9	38.9	39	38.8
	2147	39	39	38.9	38.8	39	38.9	38.8	38.8	38.7	38.7	38.6	38.8	39.2	38.7	38.8
	2149	39.2	39.2	38.9	39.1	39	38.8	38.8	38.9	38.7	38.7	39.2	38.7	38.7	38.7	38.9
	2156	39	38.9	38.9	39.1	39.2	39.3	39.2	38.8	38.6	38.8	38.9	38.7	38.9	38.8	39.1
	2162	38.9	39.3	39.3	38.9	39.2	39.4	38.9	39	39	38.9	39.4	38.9	38.8	38.7	39.1
	2166	39.2	39.1	38.9	39.3	39.1	39.1	38.8	39	38.9	39.2	39.3	39.1	38.9	38.9	38.8
	2167	38.9	38.6	38.7	38.7	38.7	38.7	38.9	38.6	38.7	38.8	38.6	38.8	38.7	38.9	38.7
	2169	39.3	39.1	38.9	39	39	39.3	38.9	39	39.2	38.9	39.1	39.1	38.8	39	39
	2172	39.9	39	38.8	39.2	38.8	38.9	39.1	39.1	38.9	38.9	38.9	39	38.9	38.8	38.6
	2175	39.1	38.8	38.6	38.6	38.9	39	38.7	38.7	38.8	38.6	38.9	39	38.7	38.9	38.6
	2177	39.1	39.5	39.3	39.3	39	39	38.9	39.1	38.7	39	39.6	38.9	39.1	38.9	39
	2193	39	39.3	39	39.1	39.3	38.9	38.8	39.5	39.1	39	38.8	38.8	38.6	38.7	39

IBR Serum Neutralization

Treatment Group	Animal Id	Study Day			
		0	27	34	49
Controls	2119	<2	<2	<2	38
	2123	<2	<2	<2	23
	2145	<2	<2	<2	76
	2148	<2	<2	<2	54
	2153	<2	<2	<2	38
	2161	<2	<2	<2	54
	2171	<2	<2	<2	76
	2178	<2	<2	<2	27
	2197	<2	<2	<2	76
	2200	<2	<2	<2	76
SC Vaccinates	2122	<2	11	16	431
	2126	<2	32	23	215
	2127	<2	16	16	215
	2131	<2	29	27	128
	2140	<2	27	23	152
	2150	<2	19	19	181
	2151	<2	23	23	304
	2155	<2	38	45	45
	2163	<2	14	16	215
	2164	<2	19	19	152
	2168	<2	36	23	181
	2174	<2	6	4	362
	2176	<2	13	19	609
	2181	<2	23	23	304
	2183	<2	9	10	304
	2185	<2	10	5	512
	2188	<2	13	11	362
	2189	<2	13	13	215
	2198	<2	32	32	181
	2199	<2	18	27	362
IM Vaccinates	2121	<2	23	27	128
	2124	<2	16	16	256
	2125	<2	16	19	45
	2128	<2	19	19	362
	2129	<2	16	16	54
	2130	<2	27	23	256
	2132	<2	13	16	304
	2133	<2	38	45	304
	2139	<2	32	45	76
	2147	<2	13	16	256
	2149	<2	45	38	181
	2156	<2	13	13	91
	2162	<2	13	10	609
	2166	<2	11	13	431
	2167	<2	27	23	108
	2169	<2	11	13	152
	2172	<2	19	23	152
	2175	<2	13	16	152
	2177	<2	6	6	256
	2193	<2	45	45	181

Titers are expressed as the greatest neutralizing dilution.

Study Type	Efficacy
Pertaining to	Herpesvirus, bovine [Infectious Bovine Rhinotracheitis (IBR)]
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR
Product Administration	
Study Animals	Bovine
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	01/08/2001

Study Type	Efficacy																							
Pertaining to	Bovine Parainfluenza type 3 Virus																							
Study Purpose	Demonstrate efficacy against virulent bovine parainfluenza type 3 virus (PI3) when challenged 28 days post-vaccination.																							
Product Administration	One dose administered intramuscularly																							
Study Animals	Six- to 8-month-old Holstein calves and seronegative to PI3 (SN antibody titer ≤ 2). Twelve placebo controls and 24 vaccinates.																							
Challenge Description	PI3 challenge on day 28.																							
Interval observed after challenge	Virus isolation from nasal swabs, serum neutralizing antibody titers, and clinical signs up to 14 days post-challenge. The study was conducted according to 9 CFR 113.309.																							
Results	Virus isolation at any occasion during the 2 week post-challenge observation period: 12/12 (100%) controls 17/24 (71%) vaccinates																							
	<table><tr><th rowspan="2">Treatment</th><th colspan="5">Post-Challenge Duration of Virus Shedding (Days)</th></tr><tr><th>Min.</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max.</th></tr><tr><td>Controls</td><td>3</td><td>5</td><td>5</td><td>6.0</td><td>6</td></tr><tr><td>Vaccinates</td><td>0</td><td>0</td><td>1</td><td>1.5</td><td>6</td></tr></table>	Treatment	Post-Challenge Duration of Virus Shedding (Days)					Min.	Q1	Median	Q3	Max.	Controls	3	5	5	6.0	6	Vaccinates	0	0	1	1.5	6
	Treatment		Post-Challenge Duration of Virus Shedding (Days)																					
		Min.	Q1	Median	Q3	Max.																		
	Controls	3	5	5	6.0	6																		
	Vaccinates	0	0	1	1.5	6																		
	Serology outcome Vaccinates: 22/25 (88%) had SN antibody titers $\geq 1:4$ on day 28. Controls: 11/11 (100%) were seronegative on day 28.																							
Individual animal data are attached.																								
USDA Approval Date	01/23/2008																							

PI3 virus isolation (log₁₀ TCID₅₀) post-challenge :

animal	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Controls														
8515	1.50 ¹	2.30	4.60	5.10	2.80	5.60	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8520	1.80	1.80	5.30	5.10	5.10	5.30	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8524	1.50	1.50	1.80	3.30	2.80	3.60	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8535	1.50	2.60	5.30	4.80	4.60	5.10	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8561	2.60	1.80	1.80	2.30	1.80	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8562	1.50	1.80	3.10	3.80	3.60	3.60	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8566	1.80	4.30	5.10	4.80	5.80	3.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8691	1.50	1.50	4.80	4.60	5.60	4.10	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8701	1.50	3.10	4.10	5.60	5.30	3.30	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50
8715	1.50	2.30	2.30	3.30	4.10	3.80	2.30	1.50	1.80	1.50	1.50	1.50	1.50	1.50
8722	2.60	3.60	4.80	5.30	4.80	4.10	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8731	3.10	3.80	5.60	5.30	5.60	4.30	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50
Vaccinates														
8491	1.50	1.50	1.50	3.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8494	1.50	1.50	1.80	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8505	1.50	1.50	1.50	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8510	1.50	2.80	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8511	1.50	1.50	2.60	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8516	1.50	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8522	1.50	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8523	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8525	1.50	2.60	3.80	3.60	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8540	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8547	1.80	2.60	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8549	1.50	1.50	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8555	1.80	1.80	1.80	1.50	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8558	1.50	3.10	2.30	2.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50

animal	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
8559	1.80	1.80	3.30	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8567	1.50	1.50	1.80	2.60	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8611	1.50	1.80	3.60	3.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8617	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8694	1.50	1.50	1.50	2.30	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8702	1.50	1.50	1.80	3.10	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8703	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8719	2.60	1.50	1.50	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8723	1.50	2.30	1.50	1.80	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
8729	2.30	1.50	3.10	3.80	3.30	2.30	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50

¹A virus titer of $\leq 1.8 \log_{10}$ TCID₅₀ is considered negative.

Red cells indicate a virus titer positive for PI3 virus

PI3 Serum Neutralizing Antibody Titers, Study Day

Challenge performed on Day 28. Day 35 is 7 days post-challenge. Day 42 is 14 days post-challenge.

Treatment	animal	Day 0	Day 7	Day 21	Day 28	Day 35	Day 42
Control Group	8515	<2	2	<2	<2	<2	144
	8520	<2	<2	<2	<2	<2	362
	8524	<2	<2	<2	<2	<2	287
	8535	<2	<2	<2	<2	3	304
	8561	<2	<2	<2	<2	6	512
	8562	<2	<2	<2	<2	<2	181
	8566	<2	<2	<2	<2	<2	362
	8691	<2	<2	<2	<2	<2	304
	8701	<2	<2	<2	<2	2	304
	8715	<2	<2	<2	<2	10	91
	8722	<2	<2	<2	<2	<2	304
	8731	<2	<2	<2	<2	2	512
Vaccinated Group	8491	<2	<2	4	10	1722	2435
	8494	<2	<2	23	38	3444	≥ 5793
	8505	<2	<2	6	16	431	2896
	8510	<2	<2	38	45	2048	4096
	8511	<2	<2	152	215	4096	≥ 4871
	8516	<2	<2	5	23	152	1722

	8522	<2	<2	64	91	362	≥4871
	8523	<2	<2	32	64	2048	≥4871
	8525	<2	<2	27	38	≥4871	≥4598
	8540	<2	2	13	64	1448	3649
	8547	<2	<2	54	108	2435	4096
	8549	<2	<2	23	54	2435	≥4871
	8555	<2	2	<2	3	215	724
	8558	<2	<2	23	45	1722	2299
	8559	<2	<2	54	45	3444	≥4598
	8567	<2	<2	10	8	1448	2896
	8611	<2	<2	16	38	1024	2435
	8617	<2	<2	23	27	64	2435
	8694	<2	<2	7	32	1024	4096
	8702	<2	<2	76	54	2048	≥5793
	8703	<2	<2	45	54	2048	3444
	8719	<2	<2	256	152	3444	≥5793
	8723	<2	<2	13	27	2896	≥4598
	8729	<2	<2	<2	<2	<2	362

Study Type	Efficacy																		
Pertaining to	Bovine Parainfluenza Type 3																		
Study Purpose	Demonstrate efficacy against virulent bovine parainfluenza type 3 virus (PI3) when challenged 29 days post-vaccination																		
Product Administration	One dose administered subcutaneously																		
Study Animals	25 vaccinated and 11 control male holstein calves, 10.5-11 months of age and seronegative to PI3 (serum neutralizing antibody titers ≤1:2).																		
Challenge Description	PI3 challenge on Day 29.																		
Interval observed after challenge	Virus isolation from nasal swabs, serum neutralizing antibody titers, and clinical signs up to 14 days post-challenge. The study was conducted per 9 CFR 113.309.																		
Results	Duration of shedding in days: <table><tr><td></td><td>Minimum</td><td>Q1</td><td>Median</td><td>Q3</td><td>Maximum</td></tr><tr><td>Vaccine</td><td>0</td><td>4</td><td>5</td><td>10</td><td>12</td></tr><tr><td>Placebo</td><td>7</td><td>8</td><td>10</td><td>11</td><td>12</td></tr></table> Serum neutralization titers: Vaccinates: 22/25 (88%) had SN antibody titers ≥1:4 on day 28. Controls: 11/11 (100%) were seronegative on day 28. Individual animal data are attached.		Minimum	Q1	Median	Q3	Maximum	Vaccine	0	4	5	10	12	Placebo	7	8	10	11	12
	Minimum	Q1	Median	Q3	Maximum														
Vaccine	0	4	5	10	12														
Placebo	7	8	10	11	12														
USDA Approval Date	07/17/2008																		

PI3 virus isolation (log₁₀ TCID₅₀), Days Post-challenge:

animal	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Controls														
9311	3.23	4.01	5.37	4.98	5.95	5.17	0.79 ¹	0.79	0.79	1.87	0.79	0.79	0.79	0.79
9313	4.20	5.37	4.98	6.54	6.54	4.78	0.98	0.79	0.79	0.98	1.67	0.79	0.79	0.79
9350	3.42	4.20	5.95	5.95	5.95	6.92	1.87	0.98	0.79	1.87	0.79	1.87	0.79	0.79
9354	2.84	8.09	4.40	4.40	4.98	5.56	1.87	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9368	1.48	3.42	5.76	6.54	6.15	6.15	0.79	0.79	0.79	0.98	0.79	1.87	0.79	0.79
9379	3.62	4.40	5.76	6.15	7.31	6.34	3.23	1.67	1.48	3.42	0.98	0.79	0.79	0.79
9380	2.64	3.42	5.17	6.92	6.34	5.76	2.45	1.48	0.79	0.98	0.79	0.79	0.79	0.79
9393	3.23	3.42	3.03	4.01	4.40	4.40	0.79	0.98	0.98	1.87	0.79	0.79	0.79	0.79
9396	2.26	5.95	6.54	7.31	6.15	5.37	0.79	0.79	0.79	1.87	1.87	0.79	0.79	0.79
9404	2.64	3.62	4.40	4.59	4.78	5.17	2.06	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9418	1.67	2.64	3.62	4.01	6.92	5.17	2.06	1.87	0.79	0.79	0.79	0.79	0.79	0.79
Vaccinates														
9306	3.23	5.76	6.34	5.56	3.42	0.79 ¹	0.79	0.79	0.98	1.48	1.87	1.87	0.79	0.79
9307	2.26	4.59	4.20	4.20	2.84	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9315	3.62	5.17	5.95	5.37	4.59	2.45	0.79	0.79	1.87	1.87	0.79	0.79	0.79	0.79
9322	1.48	1.48	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9325	3.62	3.62	3.81	4.98	3.03	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9326	1.87	2.26	0.98	2.06	0.98	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9331	2.64	2.64	4.20	4.01	2.45	2.84	0.79	1.67	0.79	0.79	0.79	0.79	0.79	0.79
9332	2.84	0.98	. ²	0.79	1.48	0.79	0.79	1.87	0.79	1.67	1.87	1.87	0.79	0.79
9337	0.79	0.79	2.06	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9342	3.23	2.84	0.79	0.98	1.67	0.79	0.79	0.79	0.79	0.98	0.79	0.79	0.79	0.79
9343	1.67	3.03	4.01	2.84	2.64	0.79	1.67	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9346	0.98	1.87	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9348	3.23	2.84	4.01	4.01	2.64	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9349	2.64	1.48	2.06	2.06	1.48	0.79	0.79	0.79	0.79	0.79	0.98	0.79	0.79	0.79
9359	0.79	1.48	2.84	3.23	1.87	0.79	0.79	0.98	0.79	0.79	0.79	0.79	0.79	0.79
9363	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9366	1.67	1.67	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9367	2.06	1.67	0.98	2.45	0.79	0.79	0.79	0.79	0.79	1.87	0.79	0.79	0.79	0.79
9376	2.84	2.06	1.87	4.20	0.79	0.79	1.48	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9377	3.03	4.20	3.62	3.23	3.23	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9382	2.26	2.06	0.79	0.79	0.79	0.79	0.79	0.79	0.98	1.87	0.79	0.79	0.79	0.79
9385	1.87	2.45	2.64	1.67	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9407	2.84	1.87	0.79	0.79	0.79	0.79	0.79	0.79	0.79	1.87	0.79	2.45	0.79	0.79

animal	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
9409	2.84	3.62	3.42	3.03	2.45	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79
9411	3.03	3.42	2.45	2.45	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79	0.79

¹ A virus titer of 0.79 log₁₀ TCID₅₀ is considered negative.

²Data point omitted due to duplicate samples. One sample yielded a result of 3.23 and the other a result of 2.06.

Red cells indicate a virus titer positive for PI3 virus

PI3 Serum Neutralizing antibody titers, Study Days.

Challenge conducted on Day 29. Day 36 is post-challenge Day 7. Day 43 is post-challenge Day 14.

animal	Day 00	Day 07	Day 21	Day 28	Day 36	Day 43
Controls						
9311	<2	<2	<2	<2	<2	362
9313	<2	<2	<2	<2	<2	304
9350	<2	<2	<2	<2	<2	181
9354	<2	<2	<2	<2	<2	91
9368	<2	<2	<2	<2	5	128
9379	<2	<2	<2	<2	<2	181
9380	<2	<2	<2	<2	<2	304
9393	<2	<2	<2	<2	<2	304
9396	<2	<2	<2	<2	2	215
9404	<2	<2	<2	<2	<2	152
9418	<2	<2	<2	<2	<2	128
Vaccinates						
9306	<2	<2	3	10	3444	4096
9307	<2	<2	27	54	4096	3444
9315	<2	<2	<2	2	724	2896
9322	<2	<2	23	45	3444	5793
9325	<2	<2	<2	3	2435	4096
9326	<2	<2	32	64	3444	4096
9331	<2	<2	<2	<2	256	724
9332	<2	<2	54	76	1722	4871
9337	<2	<2	23	45	3444	2896
9342	<2	<2	12	64	2896	6889
9343	<2	<2	16	76	4096	8192
9346	<2	<2	5	27	1722	5793
9348	<2	<2	38	64	9742	3444
9349	<2	<2	108	64	4096	6889
9359	<2	<2	4	11	2048	2896
9363	<2	<2	23	76	4096	5793

animal	Day 00	Day 07	Day 21	Day 28	Day 36	Day 43
9366	<2	<2	27	54	8192	6889
9367	<2	<2	19	54	724	1722
9376	<2	<2	10	45	4096	2435
9377	<2	<2	3	13	1722	2896
9382	<2	<2	108	108	4096	8192
9385	<2	<2	45	91	2435	6889
9407	<2	<2	16	64	2896	11585
9409	<2	<2	4	13	1218	2435
9411	<2	<2	215	304	4096	4096

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	09/19/1996

Study Type	Safety		
Pertaining to	ALL		
Study Purpose	To demonstrate safety under field conditions		
Product Administration	IBR-BVD-PI3-BRSV-VL5 or IBR-BVD-PI3-BRSV-L5 was administered either intramuscularly (IM) or subcutaneously (SQ), followed by a second vaccination 28 days later with BRSV-VL5 or BRSV-L5, respectively		
Study Animals	The study was conducted at 3 locations with 990 head of cattle (661 vaccinates and 329 controls). The animals were allotted to non-vaccinated control (329), subcutaneous (SQ) vaccination with IBR-BVD-PI3-BRSV-VL5 (210), SQ vaccination with IBR-BVD-PI3-BRSV-L5 (120), intramuscular (IM) vaccination with IBR-BVD-PI3-BRSV-VL5 (211) and IM vaccination with IBR-BVD-PI3-BRSV-L5 (120) treatment groups.		
Challenge Description	Not applicable		
Interval observed after challenge	Animals were observed for 1 to 3 hours after each vaccination, then once weekly for injection site reactions until day 49 after first injection or until resolution. Animals were also observed daily for general health observations for 49 days after the first injection.		
Results	Cattle Enrolled by Age		Vaccinate
			Control
	17-43 days		198
	10-11 months		40
	13 months		60
	Pregnant 14-27 months		200
	Pregnant 1-6 years		163
			80
	Adverse Events (AEs)		
	Number of animals		Animal with
	Enrolled		no AE
		990	(%)
	Completed the study	989	959 (96.9)
	Did not Complete the study	1 *	1
			0
	* Died from punctured abomasum before second vaccination.		

Frequency of Adverse Event observations per category of calves:

Observations	Minimum age calves (17 to 43 days of age) Number of animals				
	Controls	Vaccinates			
		SQ (1)	IM (1)	SQ (2)	IM (2)
Bloat	1	0	0	0	1
Ear drop	0	0	0	1	1
Depression	1	0	0	0	0
Diarrhea	1	0	0	0	0
Death*	0	0	0	0	1
Depression with ear drop	0	0	0	1	1
Lameness	2	0	0	0	0
Enterotoxemia	1	0	0	0	0
Draining ear	1	0	0	0	0

* Animal died from complications from bloat.

(1) Vaccination with IBR-BVD-PI3-BRSV-L5 and BRSV-L5

(2) Vaccination with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5

These Adverse Events were considered by the Regional Investigator not to be related to the use of the vaccine.

Observations	Older calves (10-13 months of age) Number of animals				
	Controls	Vaccinates			
		SQ (1)	IM (1)	SQ (2)	IM (2)
Foot Rot	1	1	1	0	0

(1) Vaccination with IBR-BVD-PI3-BRSV-L5 and BRSV-L5

(2) Vaccination with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5

These Adverse Events were considered by the Regional Investigator not to be related to the use of the vaccine.

Frequency of Adverse Event observations per category of pregnant heifers and cows:

Cattle were confirmed pregnant on day of first vaccination.

Cattle Enrolled by Trimeser	Vaccinate	Control
1	108	53
2	155	77
3	100	48

Observations	Pregnant cattle Number of animals				
	Controls	Vaccinates			
		SQ (1)	IM (1)	SQ (2)	IM (2)
Abortion	4*	2**	1	0	0
Metritis	0	1**	0	0	0

*Cause of abortions was undetermined.

** One animal was observed with abortion and metritis; cause undetermined.

(1) Vaccination with IBR-BVD-PI3-BRSV-L5 and BRSV-L5

(2) Vaccination with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5

Observations	Pregnant cattle Number of animals				
	Controls	Vaccinates			
		SQ (1)	IM (1)	SQ (2)	IM (2)
Foot rot	2	1	0	0	0
Keratitis	1	0	0	1	0
Cracked hoof	1	0	0	0	0
Lameness/edema	0	0	0	0	1

(1) Vaccination with IBR-BVD-PI3-BRSV-L5 and BRSV-L5

(2) Vaccination with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5

These Adverse Events were considered by the Regional Investigator not to be related to the use of the vaccine.

Injection Site Reactions per category of age:

Pregnant Cattle													
Controls*		SQ (1)			IM (1)			SQ (2)			IM (2)		
1st Injection													
0.5-2 cm	2-5 cm	0.5- 2 cm	2-5 cm	>5 cm	0.5- 2 cm	2-5 cm	>5 cm	0.5- 2 cm	2-5 cm	>5 cm	0.5-2 cm	2-5 cm	>5 cm
1	1	10	1	0	1	0	0	0	0	0	3**	0	0
2nd injection													
2	0	0	0	0	0	0	0	2	0	0	4	2	0

Minimum Age Calves													
Controls*		SQ (1)			IM (1)			SQ (2)			IM (2)		
1st Injection													
0.5-2 cm	2-5 cm	0.5-2 cm	2-5 cm	>5 cm	0.5-2 cm	2-5 cm	>5 cm	0.5-2 cm	2-5 cm	>5 cm	0.5-2 cm	2-5 cm	>5 cm
0	0	n/a	n/a	n/a	n/a	n/a	n/a	0	0	0	0	0	0
2nd injection													
3	0	n/a	n/a	n/a	n/a	n/a	n/a	15	2	0	5	0	0

	Older Calves														
	Controls*		SQ (1)			IM (1)			SQ (2)			IM (2)			
	1st Injection														
	0.5-2 cm	2-5 cm	0.5-2 cm	2- 5 cm	>5 cm	0.5-2 cm	2-5 cm	>5 cm	0.5- 2 cm	2- 5 cm	>5 cm	0.5- 2 cm	2- 5 cm	>5 cm	
	1	0	2**	0	4**	5**	5**	0	0	0	0	0	0	0	
	2nd injection														
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	* Controls did not have Injection Site Reactions greater than 2-5 cm														
	** In the case where an individual animal had an injection site reaction present on multiple weekly observations, only the largest reaction score is represented in the Table.														
	n/a: Minimum age calves were vaccinated only with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5														

(1): Vaccination with IBR-BVD-PI3-BRSV-L5 and BRSV-L5

(2): Vaccination with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5

The Injection Sites Reactions resolved without incident within 30 days following each vaccination with the exception of one pregnant cow, vaccinated IM with IBR-BVD-PI3-BRSV-VL5 and BRSV-VL5, which was completely resolved on day 58.

USDA Approval Date	05/14/2008
---------------------------	------------

Study Type	Safety																								
Pertaining to	ALL																								
Study Purpose	To demonstrate safety under field conditions.																								
Product Administration	Two doses administered either subcutaneously (SC) or intramuscularly (IM) 21 days apart. Second dose of vaccine consisted in BRSV only.																								
Study Animals	499 beef calves, approximately 6 to 9 months of age, at each of 3 sites, were assigned to untreated Control (97 calves), SC (202 calves) and IM (200 calves) treatment groups.																								
Challenge Description	Not Applicable																								
Interval observed after administration	Calves were observed daily for 42 days.																								
Results	<table><tr><th colspan="2">Animals Total</th><th>Animals with no Adverse Event Observations (%)</th><th colspan="2">Animals with Adverse Event Observations (%)</th></tr><tr><td>Completed the study</td><td>498</td><td>491 (98.6)</td><td colspan="2">7 (1.4)</td></tr><tr><td>Did not Complete the study</td><td>1</td><td>1</td><td colspan="2">0</td></tr><tr><td>Total</td><td>499</td><td>492 (98.6)</td><td colspan="2">7 (1.4)</td></tr></table>					Animals Total		Animals with no Adverse Event Observations (%)	Animals with Adverse Event Observations (%)		Completed the study	498	491 (98.6)	7 (1.4)		Did not Complete the study	1	1	0		Total	499	492 (98.6)	7 (1.4)	
	Animals Total		Animals with no Adverse Event Observations (%)	Animals with Adverse Event Observations (%)																					
	Completed the study	498	491 (98.6)	7 (1.4)																					
	Did not Complete the study	1	1	0																					
	Total	499	492 (98.6)	7 (1.4)																					
	<table><tr><th rowspan="2">Abnormal Health Events</th><th colspan="2">Number of Adverse Event Observations</th></tr><tr><th>Controls</th><th>Vaccinates</th></tr><tr><td>Conjunctivitis</td><td>0</td><td>1</td></tr><tr><td>Tachypnea *</td><td>1</td><td>3</td></tr><tr><td>Cough*</td><td>1</td><td>1</td></tr><tr><td>Keratoconjunctivitis</td><td>0</td><td>2</td></tr><tr><td>Respiratory disease**</td><td>1</td><td>3</td></tr></table>					Abnormal Health Events	Number of Adverse Event Observations		Controls	Vaccinates	Conjunctivitis	0	1	Tachypnea *	1	3	Cough*	1	1	Keratoconjunctivitis	0	2	Respiratory disease**	1	3
	Abnormal Health Events	Number of Adverse Event Observations																							
		Controls	Vaccinates																						
	Conjunctivitis	0	1																						
	Tachypnea *	1	3																						
	Cough*	1	1																						
	Keratoconjunctivitis	0	2																						
	Respiratory disease**	1	3																						
	*: Two calves (1 control and 1 vaccinate) had both tachypnea and cough																								
	**: The calves captured in this category are also listed under tachypnea and/or cough																								
	<table><tr><th rowspan="2">Adverse Event Observations</th><th colspan="2">Number of Animals (%)</th></tr><tr><th>Controls</th><th>Vaccinates</th></tr><tr><td>Normal</td><td>96 (98.9)</td><td>396 (98.5)</td></tr><tr><td>Abnormal</td><td>1 (1.1)</td><td>6 (1.5)</td></tr></table>					Adverse Event Observations	Number of Animals (%)		Controls	Vaccinates	Normal	96 (98.9)	396 (98.5)	Abnormal	1 (1.1)	6 (1.5)									
Adverse Event Observations	Number of Animals (%)																								
	Controls	Vaccinates																							
Normal	96 (98.9)	396 (98.5)																							
Abnormal	1 (1.1)	6 (1.5)																							
None of the Adverse Events were considered by the study Investigator to be related to vaccination.																									
No injection site reactions were observed on any animals during the study.																									
USDA Approval Date	06/24/2008																								