Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1201.22
True Name	Bovine Virus Diarrhea Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovi-Shield Gold BVD - No distributor specified
Date of Compilation Summary	August 16, 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	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

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>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</td></tr>
<tr><td>Study Animals</td><td>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.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Cattle Enrolled by Age</th><th>Vaccinate</th><th>Control</th></tr>
<tr><td>17-43 days</td><td>198</td><td>101</td></tr>
<tr><td>10-11 months</td><td>40</td><td>20</td></tr>
<tr><td>13 months</td><td>60</td><td>30</td></tr>
<tr><td>Pregnant 14-27 months</td><td>200</td><td>98</td></tr>
<tr><td>Pregnant 1-6 years</td><td>163</td><td>80</td></tr>
</table>
Adverse Events (AEs)
<table>
<tr><th colspan="2">Number of animals</th><th rowspan="2">Animal with no AE (%)</th><th rowspan="2">Animals with AE (%)</th></tr>
<tr><td>Enrolled</td><td>990</td></tr>
<tr><td>Completed the study</td><td>989</td><td>959 (96.9)</td><td>30 (3.0)</td></tr>
<tr><td>Did not Complete the study</td><td>1*</td><td>1</td><td>0</td></tr>
</table>
* Died from punctured abomasum before second vaccination.
</td></tr>
</table>

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

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions.</td></tr>
<tr><td>Product Administration</td><td>Two doses administered either subcutaneously (SQ) or intramuscularly (IM) 28 days apart. Second dose of vaccine consisted of Bacterin product only</td></tr>
<tr><td>Study Animals</td><td>307 beef calves, approximately 7 weeks (104 calves) or 9 months of age (203 calves), at each of 3 sites: Control (103 calves), SC administration of product (102 calves) and IM administration of product (102 calves) treatment groups.</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Calves were observed daily for 48 days.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th colspan="2">Animals Total</th><th>Animals with no Adverse Event Observations (%)</th><th>Animals with Adverse Event Observations (%)</th></tr>
<tr><td>Completed the study</td><td>306</td><td>301 (98.4)</td><td>5 (1.6)</td></tr>
<tr><td>Did not Complete the study</td><td>1</td><td>0</td><td>1</td></tr>
<tr><td>Total</td><td>307</td><td>301 (98.0)</td><td>6 (2)</td></tr>
</table>
<table>
<tr><th rowspan="2">Abnormal Health Events (VeDDRA Code)</th><th colspan="2">Number of Adverse Event Observations</th></tr>
<tr><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>Abnormal Breathing</td><td>0</td><td>1</td></tr>
<tr><td>Lameness</td><td>0</td><td>2*</td></tr>
<tr><td>Depression</td><td>1**</td><td>0</td></tr>
<tr><td>Dyspnea</td><td>1**</td><td>0</td></tr>
<tr><td>Death</td><td>1**</td><td>0</td></tr>
<tr><td>Anorexia</td><td>0</td><td>2</td></tr>
<tr><td>Cough</td><td>0</td><td>1</td></tr>
</table>
*: Same calf observed on 2 different days. This calf had a lame right hind (physical injury). After appearing to resolve, the lameness was observed again and did not resolve by the end of the study.
**Same calf observed on 3 different days (diagnosed post necropsy with fibronecrotizing bronchopneumonia).
</td></tr>
</table>

	<table><tr><th rowspan="2">Adverse Event Observations</th><th colspan="2">Number of Animals (%)</th></tr><tr><td>Controls</td><td>Vaccinates</td></tr><tr><td>Normal</td><td>102</td><td>199</td></tr><tr><td>Abnormal</td><td>1 (0.97)</td><td>5 (2.45)</td></tr></table> None of the Adverse Events were considered by the study Investigator to be related to vaccination. <table><tr><th rowspan="3">Treatment Group</th><th rowspan="3">Total Number of Animals</th><th colspan="4">Number of Animals with Injection Site Reactions (%)</th></tr><tr><th rowspan="2">7-week-old calves</th><th rowspan="2">9-month-old calves</th><th colspan="2">Injection Site Reaction in cm</th></tr><tr><th>< 1.5</th><th>1.5 to 5</th></tr><tr><td>Controls</td><td>103</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>SQ</td><td>102</td><td>7 (6.93)</td><td>1 (0.99)</td><td>7</td><td>1</td></tr><tr><td>IM</td><td>102</td><td>1 (0.98)</td><td>0 (0)</td><td>1</td><td>0</td></tr></table> All injection site reactions were resolved by day 48.
USDA Approval Date	06/17/2009

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions.</td></tr>
<tr><td>Product Administration</td><td>Two doses administered either subcutaneously (SC) or intramuscularly (IM) 21 days apart. Second dose of vaccine consisted in BRSV only.</td></tr>
<tr><td>Study Animals</td><td>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.</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after administration</td><td>Calves were observed daily for 42 days.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th colspan="2">Animals Total</th><th>Animals with no Adverse Event Observations (%)</th><th>Animals with Adverse Event Observations (%)</th></tr>
<tr><td>Completed the study</td><td>498</td><td>491 (98.6)</td><td>7 (1.4)</td></tr>
<tr><td>Did not Complete the study</td><td>1</td><td>1</td><td>0</td></tr>
<tr><td>Total</td><td>499</td><td>492 (98.6)</td><td>7 (1.4)</td></tr>
</table>
<table>
<tr><th rowspan="2">Abnormal Health Events</th><th colspan="2">Number of Adverse Event Observations</th></tr>
<tr><td>Controls</td><td>Vaccinates</td></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>
*: 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><td>Controls</td><td>Vaccinates</td></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>
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.
</td></tr>
<tr><td>USDA Approval Date</td><td>06/24/2008</td></tr>
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