Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	11A8.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus-Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Modified Live Virus, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis Vista Once SQ - Merck Sharpe and Dohme (MSD) Bovilis Vista Once SQ - No distributor specified Vista Once SQ - Intervet LLC-Russia - Merck Sharpe and Dohme (MSD) Vista Once SQ - Intervet Mexico S.A. de C.V. Vista Once SQ - Merck Animal Health Vista Once SQ - No distributor specified
Date of Compilation Summary	May 19, 2020

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 Virus Diarrhea Virus (BVDV) Type 1
Study Purpose	Demonstration of Efficacy of the BVDV1 fraction
Product Administration	Single dose administered subcutaneously
Study Animals	Twenty-eight calves, seronegative to BVDV1, 11-12 weeks of age, 14 vaccinates and 14 placebo controls
Challenge Description	BVDV1 strain T1186a administered intranasally 28 days after vaccination
Interval observed after challenge	Calves were observed daily for up to 14 days after challenge.
Results	Calves monitored as per 9CFR 113.311. Serology at 28 days following vaccination. Neutralizing antibodies to BVDV $\geq$1:8 are considered positive.

BVDV1 Serum Neutralization Antibody Titers

Group	Calf ID	Day Post-Challenge 28	Titer > 1:8
Vaccinate	142	1	
	144	23	Yes
	146	45	Yes
	147	512	Yes
	149	3	
	150	1	
	152	256	Yes
	153	1	
	154	91	Yes
	160	1448	Yes
	164	2896	Yes
	165	512	Yes
	166	512	Yes
	167	256	Yes
Control	143	1	
	145	1	
	148	1	
	151	1	
	155	1	
	156	1	
	157	1	
	158	1	
	159	1	
	161	1	
	162	1	
	163	1	
	168	1	
	169	1	

Note: Titer values < 1:2 are assigned a value of 1

Neutralizing Antibodies to BVDV ≥ 1:8

Vaccinates	10/14
Controls	0/14

Rectal temperature ≥ 103.5°F is considered fever. If any day during the observation period a fever was detected by rectal temperature, the calf is positive for fever.

Rectal Temperatures

		Rectal Temperature at Days Post-Challenge															
Treatment	Calf ID	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Vaccinate	142	100.5	102.8	101.1	102.2	101.0	101.0	102.3	101.4	101.6	102.1	102.3	102.5	102.1	101.6	100.6	101.3
	144	100.2	103.0	101.6	101.6	101.5	101.2	101.8	102.2	101.7	101.6	101.9	102.6	101.6	101.2	101.5	102.3
	146	100.9	102.2	99.0	102.0	100.6	101.0	101.6	100.7	101.0	102.0	102.1	101.6	100.5	101.0	100.6	101.3
	147	102.0	102.5	100.9	101.7	101.7	101.4	102.1	101.2	101.8	103.6	103.4	102.4	102.1	101.8	101.9	101.1
	149	100.9	102.3	102.0	102.6	102.0	101.3	101.9	101.5	101.5	102.0	101.8	102.1	102.1	100.9	101.8	101.4
	150	99.9	102.6	100.5	102.8	101.1	101.0	102.4	101.0	100.9	101.7	102.0	102.3	102.3	102.9	101.4	103.2
	152	100.9	103.3	101.1	102.5	102.3	101.7	102.9	101.4	101.0	102.8	102.7	102.4	101.9	102.2	101.1	100.2
	153	99.4	102.4	101.2	102.0	101.7	101.1	103.2	103.1	101.4	102.4	101.5	101.5	100.4	101.1	100.8	100.7
	154	101.0	102.9	101.5	102.5	102.5	100.5	102.5	102.3	101.7	102.3	102.1	102.1	101.3	100.5	101.7	100.7
	160	101.4	102.6	100.1	102.0	101.3	100.1	102.2	101.6	101.9	102.3	102.7	103.3	104.5	102.5	103.5	102.3
	164	100.1	101.4	100.4	102.4	100.9	100.8	101.6	100.5	100.5	102.1	101.0	101.6	100.8	101.1	100.1	101.6
	165	100.8	102.5	101.2	102.0	101.3	102.0	102.1	101.1	100.9	102.2	102.1	102.1	102.3	101.9	101.4	100.5
	166	101.2	102.7	101.1	101.9	102.2	101.2	102.0	101.2	101.2	102.0	101.5	101.6	101.8	101.7	101.6	101.6
	167	101.6	102.2	100.7	102.4	102.2	102.3	102.3	100.6	101.6	102.1	101.8	101.8	101.5	102.0	101.2	101.0
Control	143	99.1	102.5	100.4	101.9	101.8	100.9	101.5	100.8	103.2	101.8	104.0	101.8	102.2	102.1	101.7	101.0
	145	100.7	102.8	101.1	101.7	101.1	102.1	102.8	101.3	103.2	105.6	102.2	102.4	101.6	101.5	100.3	99.8
	148	101.4	102.8	100.9	101.8	100.8	102.4	102.5	101.9	103.4	104.8	102.5	102.6	101.8	101.4	101.4	100.7
	151	102.0	102.2	101.2	103.1	102.0	102.0	103.2	100.6	103.7	104.1	104.2	103.8	102.2	103.2	99.3	102.1
	155	100.6	103.6	101.7	103.1	101.4	102.9	103.2	101.7	102.6	102.8	102.0	104.3	102.3	102.6	101.8	102.0
	156	101.3	101.6	100.9	102.0	102.2	101.0	102.0	101.5	101.6	102.6	105.0	104.0	101.4	103.0	101.0	102.8
	157	100.8	102.3	101.7	102.3	102.7	101.8	101.9	101.4	102.1	101.1	102.3	102.8	103.5	102.8	101.5	101.6
	158	101.4	102.4	100.6	102.3	100.7	101.9	102.6	101.2	102.8	102.8	105.2	102.7	101.2	102.7	101.3	101.5
	159	102.2	101.8	101.2	102.2	101.8	101.8	101.9	102.1	101.7	102.9	105.2	102.2	102.2	102.8	101.3	100.9
	161	99.6	102.4	100.2	102.3	101.0	101.0	102.4	101.7	102.7	105.6	102.2	102.4	101.6	102.7	100.5	101.5
	162	101.5	102.9	101.5	101.7	101.3	101.5	102.3	101.2	102.4	102.0	102.2	103.2	103.7	101.2	101.5	100.9
	163	100.4	103.0	100.3	102.3	101.7	102.3	102.5	102.4	103.6	103.5	103.8	103.0	103.0	102.1	100.1	101.2
	168	101.6	103.2	101.3	102.5	102.3	101.3	102.2	100.9	102.8	105.8	102.4	102.2	102.0	101.5	101.1	102.1
	169	101.7	102.8	101.3	101.8	101.6	102.3	102.0	101.9	102.4	106.0	102.2	103.8	100.6	102.1	101.8	101.4

Note: Values are recorded as °F

	Temperature (≥ 103.5°F)
Vaccinates	2/14
Controls	14/14

Clinical signs (diarrhea, nasal discharge) following challenge. Signs consistent with BVD infection are indicated by N2 on any day or D1,N1 on any day.

Clinical Observation Record

Treatment	Calf ID	Clinical Signs and Scores at Day Post-Challenge															
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Vaccinate	142	0	0	0	0	0	0	0	0	0	0	N,1	0	0	0	0	0
	144	0	0	0	0	0	0	0	0	0	N,1	D,1	0	0	0	0	0
	146	0	0	0	0	0	0	C,1	0	0	0	C,1	0	0	0	0	0
	147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150	0	0	0	0	0	0	0	0	0	0	0	0	0	N,1	0	0
	152	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	154	0	0	0	0	0	0	0	0	0	0	D,1	0	0	0	0	0
	160	0	0	0	0	0	0	0	0	0	N,1	0	0	0	0	0	D,1
	164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	165	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	143	0	0	0	0	0	0	0	0	0	0	0	N,1	N,1	N,2	0	0
	145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	D,1	0
	148	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	151	0	0	0	0	0	0	0	0	N,1	0	0	N,2	0	N,2	0	0
	155	0	0	0	0	0	0	0	0	0	0	0	N,1	0	N,1	0	0
	156	0	0	0	0	0	0	0	0	0	0	0	N,1	0	0	0	0
	157	0	0	0	0	0	0	0	0	0	0	0	0	N,2	0	0	0
	158	0	0	0	0	0	0	0	0	0	0	0	0	N,2	N,2	0	0
	159	0	0	0	0	0	0	0	0	0	0	D,1 N,1	0	0	0	0	0
	161	0	0	0	0	0	0	0	0	0	0	D,1	0	0	N,2	0	0
	162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	C,1
	163	0	0	0	0	0	0	0	0	N,2	0	N,1	0	0	0	0	0
	168	0	0	0	0	0	0	0	0	0	0	0	N,2	N,2	0	0	0
	169	0	0	0	0	0	0	0	0	0	0	D,1	N,2	0	0	0	0

D=Diarrhea, 1=Soft Feces, 2=Watery Diarrhea
N=Nasal Discharge, 1=Mild, 2=Moderate
C=Cough, 1= <3 episodes, 2= >3 episodes

Clinical Signs

Vaccinates	0/14
Controls	9/14

Incidence of leukopenia following challenge. A drop of 40% from the baseline leukocyte count was the criterion for leukopenia.

Table 2: White Blood Cell Counts

Group	Calf ID	Day Post-Challenge -2	-1	0	2	4	6	8	10	Leukopenia
Vaccinate	142	10.0	9.1	7.8	8.7	10.1	8.5	8.4	7.1	
	144	18.7	18.1	16.1	17.3	18.8	16.6	15.7	15.5	
	146	10.7	9.4	9.9	12.4	11.4	10.5	11.2	8.8	
	147	13.2	10.5	8.6	9.3	NT	10.5	4.3	4.5	Yes
	149	9.2	8.3	7.5	7.4	9.0	6.8	7.4	7.1	
	150	10.7	9.2	7.6	9.3	10.6	10.0	8.1	8.5	
	152	10.7	10.7	9.4	9.9	9.3	8.9	7.5	7.5	
	153	13.6	13.3	12.2	13.4	10.2	5.5	9.5	9.3	Yes
	154	15.1	14.1	12.4	12.2	13.0	11.8	13.2	11.2	
	160	15.0	14.6	13.8	13.9	13.2	14.5	16.3	14.1	
	164	11.3	8.7	9.9	10.0	9.2	10.0	9.2	9.1	
	165	17.4	17.1	13.6	14.7	12.1	12.0	12.0	11.3	
	166	NT	29.7	25.4	23.5	23.6	23.7	20.7	20.5	
	167	15.1	15.3	11.8	14.5	13.5	12.2	11.4	13.1	
Control	143	9.7	6.2	7.0	8.9	6.4	5.8	5.5	5.7	Yes
	145	10.2	9.6	11.0	9.5	6.2	5.5	17.2	6.1	Yes
	148	7.8	8.2	7.1	8.4	5.0	5.4	6.9	7.0	Yes
	151	8.7	7.8	7.5	6.8	4.9	4.4	3.5	4.1	Yes
	155	8.2	9.3	7.7	5.4	6.5	7.0	6.5	6.5	
	156	7.3	6.2	5.9	7.3	7.7	6.0	5.8	10.8	
	157	10.9	10.2	8.4	6.2	7.0	9.7	8.3	6.2	Yes
	158	10.7	10.0	8.6	8.9	7.4	6.4	6.2	11.0	
	159	12.7	13.2	12.4	12.4	8.9	7.1	6.7	14.0	
	161	18.0	16.3	15.0	14.5	9.6	7.6	18.8	8.4	Yes
	162	18.1	17.0	15.2	15.2	12.9	11.7	11.3	8.8	
	163	15.8	17.2	13.7	12.9	8.4	8.2	6.7	7.2	Yes
	168	13.4	13.1	11.1	13.4	9.1	6.2	14.1	8.4	
	169	11.9	11.4	12.2	10.4	8.1	5.5	11.0	6.7	Yes

NT = Not Tested
Note: Values are recorded as x 10^3 / mm^3

	Number of calves
Vaccinates	2/14
Controls	8/14

Nasal shedding of BVDV following challenge. Any number greater than zero is considered positive for nasal shedding of BVDV.

Virus Shedding Measured by Virus Isolation from Nasal Swabs

Group	Calf ID	Virus Titer* at Days Post-Challenge												
		-28	-1	0	1	2	3	4	5	6	7	8	9	10
Vaccinate	142	0	0	0	0	0	0	0	0	0	0	0	0	0
	144	0	0	0	0	0	0	0	0	0	0	0	0	0
	146	0	0	0	0	0	0	0	0	0	0	0	0	0
	147	0	0	0	0	0	0	0	0	0	0	0	0	0
	149	0	0	0	0	0	0	0	0	0	0	0	0	0
	150	0	0	0	0	0	0	0	0	0	0	0	0	0
	152	0	0	0	0	0	0	0	0	0	0	0	0	0
	153	0	0	0	0	0	0	0	0	0	0	0	0	0
	154	0	0	0	0	0	0	0	0	0	0	0	0	0
	160	0	0	0	0	0	0	0	0	0	0	0	0	0
	164	0	0	0	0	0	0	0	0	0	0	0	0	0
	165	0	0	0	0	0	0	0	0	0	0	0	0	0
	166	0	0	0	0	0	0	0	0	0	0	0	0	0
	167	0	0	0	0	0	0	0	0	0	0	2.9	0	0
Control	143	0	0	0	0	0	0	1.7	0	0	2.5	2.1	2.5	0
	145	0	0	0	0	0	0	0	1.7	0	2.5	0	0	0
	148	0	0	0	0	0	0	0	0	0	3.3	2.3	1.9	0
	151	0	0	0	0	0	0	0	1.9	2.9	3.9	4.1	3.5	2.7
	155	0	0	0	0	0	0	0	0	1.7	2.7	2.5	2.9	3.9
	156	0	0	0	0	0	0	0	0	2.9	3.3	3.1	2.7	1.9
	157	0	0	0	0	0	0	0	0	0	2.9	0	3.5	3.9
	158	0	0	0	0	0	0	0	0	0	2.1	2.1	2.1	0
	159	0	0	0	0	0	1.9	0	1.7	1.7	2.7	2.3	1.7	1.7
	161	0	0	0	0	0	0	0	0	0	2.1	2.3	0	0
	162	0	0	0	0	0	0	0	0	0	0	0	0	0
	163	0	0	0	0	0	0	0	2.1	3.5	3.5	3.3	1.9	2.1
	168	0	0	0	0	0	0	0	0	0	0	1.7	0	0
	169	0	0	0	0	0	0	0	0	0	2.5	0	0	0

*Values are recorded as Log_{10} $FAID_{50}$/mL

	Number of calves shedding	**Duration**
Vaccinates	1/14	1 day
Controls	13/14	1-6 days

	Viremia of BVDV1 following challenge. A positive isolation (P) is considered positive for viremia. A negative isolation (N) is considered negative for viremia. **BVDV1 Isolation from Buffy Coat** **Vaccinate** / **Control** **Calf No.** / **Isolation** / **Calf No.** / **Isolation** 142 N 143 N 144 N 145 P 146 N 148 P 147 N 151 P 149 P 155 P 150 N 156 P 152 N 157 P 153 N 158 P 154 P 159 P 160 P 161 P 164 P 162 P 165 P 163 P 166 P 168 P 167 N 169 P P = Positive; N = Negative **Number of calves viremic** Vaccinates 6/14 Controls 13/14
USDA Approval Date	June 27, 2013

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV1.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b NY-1 strain
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	February 20, 2004

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against persistent infection of calves caused by BVDV1.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b, strain SD02 BVD09
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 23, 2005

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV1 206 days after vaccination.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b strain SD02 BVD09
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	October 6, 2005

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Viral Diarrhea Virus Type 1 (BVDV1)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against respiratory disease caused by BVDV1 1 year after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>34 seronegative calves, 3 – 4 weeks of age; 22 vaccinates, 12 controls</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with BVDV1b strain T1186a at 1 year (365 days) after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 14 days post-challenge for clinical signs of disease. White Blood Cell (WBC) count and nasal shedding were determined daily for 10 days post-challenge.</td></tr>
<tr><td>Results</td><td>
<u>Leukopenia</u>:
An affected calf was one that showed a > 40% decrease in white blood cell counts during the observation period.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>22</td><td>2</td><td>9</td></tr>
<tr><td>Controls</td><td>12</td><td>12</td><td>100</td></tr>
</table>
<u>Virus Shedding</u>:
An affected calf was one in which nasal virus shedding was detected on any day post-challenge.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>22</td><td>0</td><td>0</td></tr>
<tr><td>Controls</td><td>12</td><td>11</td><td>92</td></tr>
</table>
<u>Clinical Observations</u>:
An affected calf showed signs of acute BVDV1 (i.e. moderate to severe diarrhea, nasal discharge, and/or depression) during the observation period.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected*</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>22</td><td>1</td><td>4.5</td></tr>
<tr><td>Controls</td><td>12</td><td>6</td><td>50</td></tr>
</table>
Requirements per 9 CFR 113.311 were met.

Raw data shown on attached pages.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 11, 2014</td></tr>
</table>

White Blood Cell (WBC) Counts

		WBC Counts (x 10^3/mL) Day Post-Challenge										
Group	ID	-2	-1	0	2	3	4	5	6	7	8	10
Controls	308	16.7	13.2	10.5	11.1	**5.1**	**4.9**	6.1	5.5	8.2	8.2	9.3
	315	10.9	7.1	7.9	6.2	**4.8**	**3.7**	**4.6**	**4.4**	5.2	7.9	6.4
	319	11.6	9.5	8.7	9.5	**5.2**	**5.4**	6.5	6.5	6.5	8.9	7.0
	320	10.6	8.4	6.2	6.8	**3.9**	**3.3**	**4.4**	**3.7**	5.3	6.0	6.4
	322	12.5	11.0	9.1	11.5	**5.3**	**3.7**	**5.9**	**5.6**	7.6	11.6	7.8
	325	11.4	9.3	8.0	7.3	**4.1**	**3.9**	**4.7**	**4.1**	**4.8**	**1.9**	6.1
	327	14.7	12.7	9.8	11.6	**7.1**	**5.3**	8.3	**6.7**	7.9	9.2	9.7
	330	12.6	10.4	9.2	7.8	**4.8**	**4.6**	7.1	**5.4**	**5.9**	7.8	6.8
	334	10.0	10.1	9.4	10.7	6.7	**5.6**	6.8	5.9	7.0	9.5	7.7
	336	11.3	8.8	7.9	7.4	**4.8**	**3.9**	**4.7**	**3.7**	**4.3**	6.2	6.1
	337	11.4	8.8	7.5	9.3	**4.6**	**4.1**	**5.1**	**4.5**	**4.5**	6.9	9.1
	338	13.7	11.3	10.4	10.2	**6.2**	**5.6**	**5.0**	**5.2**	**5.6**	7.7	8.8
	Ave.:	**12.3**	**10.1**	**8.7**	**9.1**	**5.2**	**4.5**	**5.8**	**5.1**	**6.1**	**7.7**	**7.6**
Vaccinates	309	13.4	6.5	8.0	8.1	8.4	7.7	8.5	7.8	7.3	8.0	8.7
	310	13.6	10.7	9.6	9.9	8.9	8.7	11.0	9.8	11.1	8.0	9.9
	311	13.4	10.5	7.7	8.2	**2.2**	8.7	8.5	7.1	9.3	10.3	7.7
	312	12.5	11.3	8.7	9.1	9.1	8.0	6.5	7.3	9.2	8.0	10.3
	313	10.2	9.4	7.4	6.8	6.4	6.3	7.6	8.4	8.8	8.3	8.6
	314	9.6	10.6	8.8	9.9	7.0	8.5	9.0	7.8	7.3	7.4	8.7
	316	11.2	11.0	8.2	9.9	9.8	9.3	8.8	8.5	8.3	8.0	9.3
	317	13.3	8.3	9.6	10.6	8.9	10.5	9.2	9.5	10.1	10.9	12.1
	318	13.4	9.4	8.2	9.3	7.7	7.8	9.0	7.2	8.7	9.2	10.1
	321	11.7	11.2	7.3	11.1	8.7	7.3	6.9	7.4	9.3	9.6	12.0
	323	14.7	13.6	12.3	12.7	11.0	10.9	9.8	9.4	8.9	8.1	10.9
	324	15.5	13.7	11.6	10.1	11.1	10.1	11.2	10.6	10.1	10.1	10.2
	326	12.9	9.8	7.3	8.6	8.0	8.1	9.1	8.1	7.5	8.1	11.3
	328	14.4	14.0	10.6	11.4	10.1	10.0	9.5	9.6	9.5	10.4	9.8
	329	11.9	11.4	11.4	12.1	9.4	10.4	9.4	8.7	8.2	10.4	10.4
	331	10.1	8.5	7.9	8.5	7.9	7.7	9.1	6.5	7.6	7.5	7.5
	332	11.2	11.0	10.2	9.5	9.4	9.3	9.0	8.5	9.5	9.0	8.7
	333	14.7	11.0	11.8	12.2	12.1	10.7	9.6	9.5	10.3	10.3	10.1
	335	9.3	9.7	8.6	8.7	7.1	8.2	7.8	7.0	5.9	6.1	7.7
	339	11.8	9.6	8.7	9.1	8.4	6.7	7.9	6.8	7.2	7.6	8.4
	340	13.8	10.8	9.9	7.6	**6.7**	7.4	7.6	7.3	7.6	9.0	9.1
	341	8.4	11.3	11.4	13.5	10.2	11.2	10.8	8.6	8.1	9.5	8.4
	Ave.:	**12.3**	**10.6**	**9.3**	**9.9**	**8.6**	**8.8**	**8.9**	**8.2**	**8.6**	**8.8**	**9.5**

Bold indicates leukopenia (>40% reduction in WBC count compared to baseline count)

Nasal Swab Virus Shedding Results

		Nasal Virus Titer (Log_{10} $TCID_{50}$/mL) Day Post-Challenge												
Group	ID	Vac[1]	-1	0	1	2	3	4	5	6	7	8	9	10
Controls	308	0	0	0	0	0	0	0	0	0	1.7	0	0	0
	315	0	0	0	0	0	0	0	1.9	0	1.9	1.7	0	1.9
	319	0	0	0	0	0	0	0	0	1.7	2.1	1.7	0	0
	320	0	0	0	0	0	0	0	0	0	1.7	0	0	0
	322	0	0	0	0	0	0	0	0	0	0	1.7	0	0
	325	0	0	0	0	0	0	0	0	1.7	2.1	1.7	1.7	2.1
	327	0	0	0	0	0	0	0	0	0	0	1.7	0	0
	330	0	0	0	0	0	0	0	0	0	1.9	1.9	2.1	1.9
	334	0	0	0	0	0	0	0	0	0	0	0	0	0
	336	0	0	0	0	0	0	0	0	1.9	2.3	2.3	1.7	0
	337	0	0	0	0	0	0	0	0	1.7	1.7	1.7	0	0
	338	0	0	0	0	0	0	0	0	0	3.1	1.7	1.7	1.9
	Ave.:	0	0	0	0	0	0	0	0	0.6	1.5	1.3	0.6	0.7
Vaccinates	309	0	0	0	0	0	0	0	0	0	0	0	0	0
	310	0	0	0	0	0	0	0	0	0	0	0	0	0
	311	0	0	0	0	0	0	0	0	0	0	0	0	0
	312	0	0	0	0	0	0	0	0	0	0	0	0	0
	313	0	0	0	0	0	0	0	0	0	0	0	0	0
	314	0	0	0	0	0	0	0	0	0	0	0	0	0
	316	0	0	0	0	0	0	0	0	0	0	0	0	0
	317	0	0	0	0	0	0	0	0	0	0	0	0	0
	318	0	0	0	0	0	0	0	0	0	0	0	0	0
	321	0	0	0	0	0	0	0	0	0	0	0	0	0
	323	0	0	0	0	0	0	0	0	0	0	0	0	0
	324	0	0	0	0	0	0	0	0	0	0	0	0	0
	326	0	0	0	0	0	0	0	0	0	0	0	0	0
	328	0	0	0	0	0	0	0	0	0	0	0	0	0
	329	0	0	0	0	0	0	0	0	0	0	0	0	0
	331	0	0	0	0	0	0	0	0	0	0	0	0	0
	332	0	0	0	0	0	0	0	0	0	0	0	0	0
	333	0	0	0	0	0	0	0	0	0	0	0	0	0
	335	0	0	0	0	0	0	0	0	0	0	0	0	0
	339	0	0	0	0	0	0	0	0	0	0	0	0	0
	340	0	0	0	0	0	0	0	0	0	0	0	0	0
	341	0	0	0	0	0	0	0	0	0	0	0	0	0
	Ave.:	0	0	0	0	0	0	0	0	0	0	0	0	0

[1] Prior to vaccination, Study day 0

Clinical Observations Post-Challenge

		Day Post-Challenge															
Group	ID	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Affected*
Controls	308	0	0	0	0	0	0	0	C1	0	N2	0	D2	D2,N1	0	0	0	Yes
	315	0	C1	0	0	0	0	C1	C1	C2	C2	C2	N2,C1	N2,C2	0	0	C2	Yes
	319	0	0	0	0	0	0	0	0	N2	N2	0	N1,C1	N1	N1	0	0	Yes
	320	0	0	0	0	0	0	0	0	0	0	N1	0	0	0	0	0	No
	322	0	0	0	0	0	0	0	0	0	N1	0	0	0	0	0	0	No
	325	0	0	0	0	0	0	0	0	0	0	N1	N1	N1	0	C1	0	No
	327	0	0	0	0	0	N1	N1	N1	0	N2	0	N1	N1	N2	0	0	Yes
	330	0	0	0	0	0	0	0	0	0	0	0	0	D2,N1	D1	0	0	Yes
	334	0	0	0	0	0	0	C1	0	0	C2	0	0	0	N1	0	0	No
	336	0	0	0	0	0	0	0	0	0	N1,C1	0	0	0	0	0	0	No
	337	0	0	0	0	0	0	0	0	0	0	C1	0	0	0	0	0	No
	338	0	0	0	0	0	0	0	0	0	0	N1	D2,N1	0	0	0	0	Yes
Vaccinates	309	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	0	No
	310	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	311	0	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	No
	312	0	0	0	0	0	0	0	0	0	0	0	0	C1	0	0	0	No
	313	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	314	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	317	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	321	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	323	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	324	0	0	0	0	0	N1	0	0	0	N1	N1	0	C1	0	0	0	No
	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	328	0	0	0	0	0	0	0	0	0	0	0	D1	C1	0	0	0	No
	329	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	331	0	0	0	0	0	0	0	N1	N1	D1,N1	D2	0	0	0	0	0	Yes
	332	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	0	No
	333	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	339	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	0	No
	340	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
	341	0	0	0	0	0	0	0	C1	0	0	0	0	0	0	0	0	No

Clinical Description: 0 = Normal, C = Cough, D = Diarrhea, N = Nasal Discharge

*An affected calf is one with a moderate to severe clinical sign of diarrhea, nasal discharge or depression on any post-challenge day

Clinical Score	Diarrhea	Nasal Discharge	Depression	Dyspnea	Cough
0	None	None	None	None	None
1	Soft feces	Serous discharge	Moves slowly, head down	Short and rapid	< 3 episodes
2	Watery diarrhea	Mucopurulent discharge	Tends to lie down, staggers	Labored, noticeable abdominal	> 3 episodes
3	Watery and bloody diarrhea	Severe mucopurulent discharge	Stands with difficulty	Very labored, grunting	NA

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV2.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV2a strain 1373
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	December 10, 2003

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV2)
Study Purpose	To demonstrate efficacy against persistent infection of calves caused by BVDV2
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 2 strain SD02 BVD05
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	April 25, 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>To demonstrate efficacy against respiratory disease caused by BVDV2 1 year after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>40 calves, 3 months of age; 20 vaccinates, 20 controls</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with BVDV2a strain 1373 384 days after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 14 days post-challenge for clinical signs of disease.</td></tr>
<tr><td>Results</td><td>
Mortality:
An affected calf was one that died or was humanely euthanized due to severe BVDV2 disease during the post-challenge period.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>20</td><td>0</td><td>0</td></tr>
<tr><td>Controls</td><td>20</td><td>11*</td><td>55</td></tr>
</table>
* An additional 7 control calves either died or were euthanized by day 16 post-challenge (2 days after the post-challenge observation period) due to severe BVDV2 clinical disease, bringing the mortality rate to 90% for control calves.

Leukopenia:
An affected calf was one that showed a post-challenge WBC count ≤ 60% of the baseline WBC count, and/or ≤ 4.0 x 10^3 WBC/µL.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>20</td><td>3</td><td>15</td></tr>
<tr><td>Controls</td><td>20</td><td>19</td><td>95</td></tr>
</table>
Virus Shedding:
An affected calf was one in which nasal virus shedding was detected on any day post-challenge.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>20</td><td>0</td><td>0</td></tr>
<tr><td>Controls</td><td>20</td><td>20</td><td>100</td></tr>
</table>
Clinical Observations:
An affected calf showed moderate to severe signs of acute BVD2 (i.e. moderate to severe diarrhea, nasal discharge, depression, dyspnea, oral lesions, or mortality) on any day during the observation period.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected*</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>20</td><td>2</td><td>10</td></tr>
<tr><td>Controls</td><td>20</td><td>20</td><td>100</td></tr>
</table>
Raw data shown on attached pages.
</td></tr>
<tr><td>USDA Approval Date</td><td>September 19, 2014</td></tr>
</table>

White Blood Cell (WBC) Counts (x 10^3/µL)

		Day Post-Challenge														
Group	ID	-2	-1	0	Baseline	2	3	4	5	6	7	8	9	10	12	14
Controls	195	11.1	11.0	11.1	11.1	11.4	6.7	6.6	6.1	6.3	7.1	6.7	4.9	4.3	4.4	3.9
	198	10.6	11.2	10.7	10.8	9.4	5.8	5.2	4.9	5.0	4.8	4.0	6.4	7.0	Dead	Dead
	199	8.4	8.4	9.8	8.9	8.6	5.2	5.3	5.5	5.8	4.9	3.9	4.0	2.7	3.1	Dead
	202	7.0	6.5	7.0	6.8	7.4	3.7	4.4	4.1	4.3	4.3	3.4	4.8	6.5	4.3	7.2
	204	11.1	8.8	16.7	12.2	14.7	8.0	8.5	8.8	8.4	10.0	7.4	5.8	4.0	4.4	Dead
	206	9.1	8.9	8.5	8.8	8.5	4.4	4.9	4.7	4.5	4.9	3.5	2.5	2.7	2.2	Dead
	207	9.9	10.5	9.9	10.1	9.8	5.3	6.7	7.5	6.6	6.2	5.5	3.9	3.6	5.2	Dead
	209	11.9	11.5	10.7	11.4	11.6	6.6	8.5	6.8	7.4	7.1	5.1	4.0	4.6	Dead	Dead
	211	8.1	8.5	8.1	8.2	7.8	4.9	6.6	5.5	5.1	4.9	3.8	3.2	2.4	1.9	Dead
	212	11.4	13.5	9.9	11.6	7.7	5.7	5.0	6.1	6.1	6.0	5.3	3.9	3.0	3.7	3.0
	213	10.5	8.6	8.4	9.2	9.8	6.5	6.8	6.3	6.3	5.0	5.3	2.8	2.1	2.2	1.4
	218	10.9	10.3	10.3	10.5	9.6	5.6	6.5	6.4	6.1	5.8	8.3	11.3	10.7	7.5	8.8
	219	14.5	15.0	14.1	14.5	14.5	10.7	11.5	10.2	10.8	8.4	8.9	5.6	5.0	6.6	Dead
	220	9.2	8.8	8.4	8.8	8.3	7.1	6.5	5.5	5.6	5.2	5.6	4.9	3.6	3.9	3.0
	221	9.3	10.0	10.3	9.9	8.1	6.5	6.0	6.9	6.1	4.7	3.2	2.8	2.6	1.6	Dead
	222	11.1	8.3	8.7	9.4	10.0	5.6	6.1	6.2	7.1	6.0	5.7	5.6	11.1	Dead	Dead
	223	16.2	14.7	15.9	15.6	13.6	12.0	12.3	11.4	11.2	9.7	9.4	6.8	5.3	4.2	Dead
	227	12.1	10.6	10.6	11.1	12.0	8.7	7.9	8.7	8.4	7.8	7.6	9.6	10.1	10.6	9.2
	230	11.6	11.2	11.3	11.4	11.9	9.3	8.6	8.5	8.4	8.4	6.2	6.4	7.5	8.2	13.0
	231	7.3	7.1	7.3	7.2	7.6	6.9	6.0	6.5	5.2	5.1	3.8	3.9	3.4	3.0	1.8
	Ave.:				10.4	10.1	6.8	7.0	6.8	6.7	6.3	5.6	5.2	5.1	4.5	5.7
Vaccinates	194	18.4	17.3	18.7	18.1	18.9	16.7	13.9	15.1	16.7	18.7	16.2	16.4	17.2	16.4	17.1
	196	8.1	7.5	8.4	8.0	9.4	10.5	7.6	5.9	7.3	6.9	7.7	7.6	8.3	8.8	8.1
	197	14.6	13.7	14.0	14.1	13.5	13.8	13.2	12.5	11.3	12.5	11.6	13.1	13.1	13.3	13.4
	200	8.1	8.7	10.4	9.1	12.5	9.3	9.0	8.4	8.0	7.7	9.6	8.5	7.9	7.4	7.2
	201	10.8	9.8	8.5	9.7	8.2	7.3	5.2	6.5	5.8	7.9	8.4	8.3	7.8	7.1	7.4
	203	9.8	10.7	10.5	10.3	8.4	5.1	5.4	5.6	6.7	6.6	10.6	10.7	8.0	8.8	6.6
	205	9.3	10.7	10.9	10.3	9.3	8.0	6.8	5.5	6.4	9.6	10.5	10.6	9.8	9.5	9.9
	208	8.6	9.9	8.5	9.0	8.3	9.0	9.7	7.1	7.7	7.0	8.9	9.2	9.8	6.9	7.6
	210	11.1	11.0	11.1	11.1	11.9	9.7	8.9	9.1	10.4	10.0	11.1	9.5	9.1	9.7	9.0
	214	15.5	18.2	15.7	16.5	22.6	16.4	15.1	13.1	13.0	15.4	15.8	15.4	18.6	14.1	14.2
	215	8.4	9.5	8.8	8.9	8.3	8.0	6.9	6.5	6.6	8.4	8.7	9.1	8.9	8.9	8.9
	216	10.1	10.5	11.0	10.5	12.1	9.8	7.0	6.7	6.8	8.2	10.3	9.1	9.1	8.2	8.6
	217	12.1	13.6	13.2	13.0	13.4	13.7	12.5	11.2	12.4	14.7	14.1	12.8	10.2	10.9	12.3
	224	10.4	9.0	8.6	9.3	10.7	9.5	7.7	7.5	7.2	9.3	7.7	8.1	10.5	8.8	10.5
	225	10.7	11.5	10.5	10.9	10.3	11.3	10.5	8.0	7.8	7.5	10.8	10.6	12.5	10.7	10.4
	226	9.2	8.3	9.7	9.1	10.4	9.9	9.1	9.1	8.4	8.4	8.7	9.3	10.2	8.7	9.0
	228	8.3	8.0	7.4	7.9	8.4	7.7	6.4	5.4	6.4	7.1	9.4	7.9	8.6	7.2	7.1
	229	7.4	7.6	7.0	7.3	7.2	7.3	7.0	7.3	6.8	6.6	6.9	6.3	5.5	7.1	7.5
	232	11.1	10.7	11.3	11.0	10.7	10.0	8.7	8.5	8.2	12.0	10.3	9.3	9.4	7.6	8.0
	233	15.3	16.2	14.0	15.2	14.1	13.8	11.6	11.6	11.2	13.9	13.4	14.2	14.1	14.8	12.9
	Ave.:				11.0	11.4	10.3	9.1	8.5	8.8	9.9	10.5	10.3	10.4	9.7	9.8

Bold indicates leukopenia (WBC count ≤ 60% of baseline count, and/or WBC count ≤ 4.0 x 10^3/µL)

Nasal Swab Virus Shedding Results

		Nasal Virus Titer (Log_{10} $FAID_{50}$/mL) Day Post-Challenge														
Group	ID	Vac.[1]	-1	0	1	2	3	4	5	6	7	8	9	10	12	14
Controls	195	0	0	0	0	0	0	0	0	0	0	1.7	2.3	2.5	1.7	C[2]
	198	0	0	0	0	0	0	0	0	1.7	2.5	2.5	2.5	1.7	Dead	Dead
	199	0	0	0	0	0	0	0	0	0	0	1.9	2.5	2.5	0	Dead
	202	0	0	0	0	0	0	1.7	0	1.9	2.3	1.7	2.3	2.1	0	0
	204	0	0	0	0	0	0	0	0	0	0	1.9	2.9	3.9	2.5	Dead
	206	0	0	0	0	0	0	0	0	0	2.1	0	2.1	3.1	0	Dead
	207	0	0	0	0	0	0	0	0	1.9	0	2.5	2.7	2.9	2.7	Dead
	209	0	0	0	0	0	0	0	0	0	1.7	2.3	2.5	2.9	Dead	Dead
	211	0	0	0	0	0	0	0	1.7	1.9	0	2.1	3.5	3.5	3.9	Dead
	212	0	0	0	0	0	0	0	0	0	0	1.7	2.7	2.3	0	0
	213	0	0	0	0	0	0	0	0	0	1.9	2.3	3.5	3.5	3.3	2.1
	218	0	0	0	0	0	0	0	0	0	0	0	1.7	0	0	0
	219	0	0	0	0	0	0	0	0	0	1.9	2.1	0	2.7	1.7	Dead
	220	0	0	0	0	0	0	0	0	0	0	2.3	2.7	3.5	3.5	3.9
	221	0	0	0	0	0	0	0	1.7	0	2.3	2.1	3.9	3.5	4.1	Dead
	222	0	0	0	0	0	0	0	0	0	1.9	2.5	2.9	2.5	Dead	Dead
	223	0	0	0	0	0	0	0	0	0	0	1.9	2.3	2.5	0	Dead
	227	0	0	0	0	0	0	0	0	0	0	0	0	1.9	0	0
	230	0	0	0	0	0	0	0	0	0	1.9	1.7	3.1	1.9	0	0
	231	0	0	0	0	0	0	0	0	0	0	0	3.1	2.3	1.9	1.7
	Ave.:	**0**	**0**	**0**	**0**	**0**	**0**	**0.1**	**0.2**	**0.4**	**0.9**	**1.7**	**2.5**	**2.6**	**1.5**	**1.0**
Vaccinates	194	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	196	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	197	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	201	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	203	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	208	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	210	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	215	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	216	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	217	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	224	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	225	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	226	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	228	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	229	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	232	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	233	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Ave.:	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

[1]Prior to vaccination, Study day 0
[2]Contaminated sample

Clinical Observation Post-Challenge

Group	ID	Day Post-Challenge															Affected	Died/Euthanized
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	195	0	0	0	0	0	0	0	0	N1	N1	N1	N1	N2,D2,A1,OL3	N2,A1,OL3	N2,D3,A1,R1,OL3	D3,A2,R2,OL3	Yes	No[1]
	198	0	0	0	0	0	0	0	0	N1,C1	N1	N1	N1,OL1	Died	NA	NA	NA	Yes	Yes
	199	0	0	0	0	0	0	0	N1	N1	N1	N1	N1	N3,OL1	N3,D2,A3,R2,OL3,Euth.	NA	NA	Yes	Yes
	202	0	0	0	0	0	N1	0	0	0	N1	N2,D1	N1	N3,A1,OL1	N3,D2,OL2	N1,A1	N2,A1,OL2	Yes	No[1]
	204	N1	0	0	0	0	0	0	N1	N1	N1	N1,D1	N2,OL2	N1,D1,A1,OL2	N3,D1,A2,R2,OL2	Died	NA	Yes	Yes
	206	0	0	0	0	N1	N1	N1	N1	N1	0	N1	N1	N3,OL2	N3,D1,A2,R2,OL2	Died	NA	Yes	Yes
	207	N1	0	0	0	0	N1	0	0	N1	N1,D1	N1	N1	N1,D2,A1	N3,D3,R2,A3,Euth.	NA	NA	Yes	Yes
	209	0	0	0	0	0	0	0	0	0	N1	N1	N1,D2	N1,D2,A1,R2,OL1	Died	NA	NA	Yes	Yes
	211	0	0	0	0	0	0	0	N1	N1,D1	N1	N1	N1	N1,D2,A1	N3,A1,OL2	N2,D2,A2,OL3,Euth.	NA	Yes	Yes
	212	N1	0	0	0	0	0	0	0	N1	N1	N1	N1	N3,D1	N1	N2,D1,A1	N1,A1,OL1	Yes	No[1]
	213	N1	0	0	0	0	0	0	0	N1	N1	N1	N2,OL2	N1,OL2	N1,A1,OL2	A1,OL3,Bleeding	N1,A2,R2,OL3	Yes	No[1]
	218	N1	N1	0	0	0	0	N1	0	N1	N1	N2	N2	N1	N1	N1	N1	Yes	No
	219	0	0	0	N1	0	N1	0	N1	0	N1	N1	N3,OL2	N2,A1,OL2	N2,D2,A3,R2,OL2,Euth.	NA	NA	Yes	Yes
	220	N1	0	0	0	0	0	0	0	0	N1	N1	N1	N1	N2,A1	N3,A1	N2,A1,OL2	Yes	No[1]
	221	0	N1	0	0	0	0	N1	N2	N2	N2	N1	N1	N2,D1,A1,OL3	N2,OL3	Died	NA	Yes	Yes
	222	N1	0	0	0	0	N1	N1	0	N1	N1	N2	N1,OL1	N1	Died	NA	NA	Yes	Yes
	223	N1	0	0	0	0	0	0	0	N1	N1	N1	N1	N1,A2,R2	N1,A3,R3,Euthanized	NA	NA	Yes	Yes
	227	0	0	0	0	0	0	0	0	N1	N1	N1	N1	N2,D2,A1,OL1	N1,D2,A1	0	N1,A1	Yes	No
	230	0	0	0	0	N1	N1	N2	N2	N2	N1	N2	N2	N2,A1,R1,OL1	N1,OL1	N2,A2,OL1, Bleeding	A2,OL2	Yes	No[1]
	231	0	N1	0	0	0	0	0	0	N1	N1	N1	N1	N1,D1	N2,OL3	N3,D2,A1	N1,D2,A1	Yes	No[1]
Vaccinates	194	0	0	0	0	0	0	0	0	0	0	N1	N1	0	0	N1	0	No	No
	196	0	N1	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	N1	N1	No	No
	197	0	0	0	0	0	0	0	0	N1	0	0	N1	N1	N1	N1	0	No	No
	200	0	0	0	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	0	No	No
	201	N1	N1	0	0	0	0	0	0	N1	0	0	N1	N1	N1	0	0	No	No
	203	0	0	0	0	0	0	0	0	N1	N1,D1	D1	N1,D1	N1,D1	0	0	0	No	No
	205	N1	N1	N1	N1	0	N1	N2	N2	N2	N1	N1	N1	0	N2	N1	N1	Yes	No
	208	0	0	0	0	0	0	0	0	N1	N1	0	N1	N1	N1	0	0	No	No
	210	0	N1	0	0	0	0	N1	0	0	0	0	N1	N1	N1	N1	0	No	No
	214	0	N1	0	0	0	N1	0	0	N1	N1	N1	N1	N1	N1	N1	0	No	No
	215	0	N1	0	0	0	N1	N1	N1	N1	N1	N1,D1	N1	N1,D1	N1,D1	N1,D1	N1	No	No
	216	0	0	0	0	0	0	0	0	N1	N1	0	N1	N1,D1	0	N1	0	No	No
	217	0	0	0	0	0	0	0	0	N1	D1	N1,D1	N1	N1	N1	N1	0	No	No
	224	0	0	0	0	0	0	0	0	N1	0	N1	N1	N1,D1	0	N1,D1	N1	No	No
	225	0	0	0	N1	0	0	0	0	0	0	0	N1	N1	N1	N1	0	No	No
	226	0	0	0	0	0	0	0	0	0	0	0	N1	N1,D1	0	N1	0	No	No
	228	N1	0	0	0	0	N1	0	0	0	N1,D1	0	N1	N1	N1	0	0	No	No
	229	0	0	0	0	0	0	0	0	N1,D1	0	0	N2	N1	N1	N2	N1	Yes	No
	232	0	N1	0	0	0	0	0	0	N1	0	0	N1	N1	N1	0	0	No	No
	233	N1	0	0	0	0	0	N1	N1	0	N1	N1	N1	N1	0	N1	0	No	No

Clinical Descriptions: 0 = Normal, N = Nasal Discharge, D = Diarrhea, A = Depression, R = Dyspnea, OL = Oral Lesion, NA = Not observed; Severity: 1 = mild, 2 = moderate, 3 = severe

[1]Animal died or was euthanized by 16 days post-challenge (20-Dec-13)

Clinical Score	Diarrhea	Nasal Discharge	Depression (Attitude)	Dyspnea	Oral Lesions
0	None	None	Normal	None	None
1	Soft feces	Serous discharge	Moves slowly, head down	Short and rapid	Erosions on oral mucosa
2	Watery diarrhea	Mucopurulent discharge	Tends to lie down, staggers	Labored, abdominal breathing	Ulcerations on oral mucosa
3	Watery and bloody diarrhea	Severe mucopurulent	Stands with difficulty	Very labored, grunts or raspy breathing	Hemorrhages on oral mucosa

<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>To demonstrate efficacy against fetal infection caused by BVDV2 206 days after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route 28 days prior to breeding.</td></tr>
<tr><td>Study Animals</td><td>46 seronegative heifers, 28 vaccinates and 18 controls.</td></tr>
<tr><td>Challenge Description</td><td>All heifers were challenge with BVDV2 strain IV809-04 at 164-178 days of gestation.</td></tr>
<tr><td>Interval observed after challenge</td><td>Blood samples were collected on days 0, 5 through 10 post challenge for virus isolation. Fetuses were collected on day 60 after challenge.</td></tr>
<tr><td>Results</td><td>Virus Isolation on heifers:
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>28</td><td>2</td><td>7</td></tr>
<tr><td>Controls</td><td>18</td><td>18</td><td>100</td></tr>
</table>
Virus Isolation from fetal samples:
Calves (fetuses) were considered positive if virus was isolated from any fetal tissue (lung, spleen, thymus, kidney, buffy coat).
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>28</td><td>2</td><td>4</td></tr>
<tr><td>Controls</td><td>18</td><td>17</td><td>94</td></tr>
</table>
Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>October 4, 2007</td></tr>
</table>

Viremia of Challenged Heifers

(Vaccinate Group)

Heifer Number	Isolation of BVDV from Buffy-coats at Days post-challenge						
	0	5	6	7	8	9	10
1536	0	0	0	0	0	0	0
1538	0	0	0	0	0	0	0
1541	0	0	0	0	0	0	0
1544	0	0	1	0	0	0	0
1545	0	0	0	0	0	0	0
1556	0	0	0	0	0	0	0
1558	0	0	0	0	0	0	0
1562	0	0	0	0	0	0	0
1566	0	0	0	0	0	0	0
1567	0	0	0	0	0	0	0
1569	0	0	0	0	0	0	0
1570	0	0	0	0	0	0	0
1575	0	0	0	0	0	0	0
1581	0	0	0	0	0	0	0
1582	0	0	0	0	0	0	0
1585	0	0	1	0	0	0	0
1594	0	0	0	0	0	0	0
1596	0	0	0	0	0	0	0
1597	0	0	0	0	0	0	0
1598	0	0	0	0	0	0	0
1599	0	0	0	0	0	0	0
1601	0	0	0	0	0	0	0
1605	0	0	0	0	0	0	0
1606	0	0	0	0	0	0	0
1607	0	0	0	0	0	0	0
1608	0	0	0	0	0	0	0
1609	0	0	0	0	0	0	0
1614	0	0	0	0	0	0	0

0=negative; 1=positive.

(Control Group)

Heifer Number	Isolation of BVDV from Buffy-coats at Days post-challenge						
	0	5	6	7	8	9	10
1540	0	1	1	1	1	0	0
1542	0	1	1	0	1	0	0
1543	0	1	1	1	1	0	1
1546	0	0	1	1	1	0	0
1549	0	1	1	1	1	1	0
1553	0	1	1	1	1	1	0
1557	0	0	1	1	1	0	0
1571	0	1	1	1	1	0	0
1572	0	1	1	0	1	0	0
1573	0	1	1	1	1	0	0
1574	0	1	1	1	0	1	0
1577	0	1	1	1	0	0	0
1586	0	1	1	1	0	0	0
1590	0	1	1	1	0	0	0
1591	0	1	1	1	1	1	0
1593	0	1	1	1	1	1	0
1595	0	1	1	1	1	1	0
1615	0	1	0	0	0	1	0

0=negative; 1=positive.

Virus Isolation from Fetal Samples

Groups	Heifer ID	Virus isolations					VI Results
		Thymus	Spleen	Lung	Kidney	Buffy-coats	
Vaccinate	1536	0	0	0	0	0	0
	1538	0	0	0	0	0	0
	1541	0	0	0	0	0	0
	1544	0	0	0	0	0	0
	1545	1	1	1	0	1	1
	1556	0	0	0	0	0	0
	1558	0	0	0	0	0	0
	1562	0	0	0	0	0	0
	1566	0	0	0	0	0	0
	1567	0	0	0	0	0	0
	1569	0	0	0	0	0	0
	1570	0	0	0	0	0	0
	1575	0	0	0	0	0	0
	1581	0	0	0	0	0	0
	1582	0	0	0	0	0	0
	1585	0	0	0	0	0	0
	1594	0	0	0	0	0	0
	1596	0	0	0	0	0	0
	1597	0	0	0	0	0	0
	1598	0	0	0	0	0	0
	1599	0	0	0	0	0	0
	1601	0	0	0	0	1	1
	1605	0	0	0	0	0	0
	1606	0	0	0	0	0	0
	1607	0	0	0	0	0	0
	1608	0	0	0	0	0	0
	1609	0	0	0	0	0	0
	1614	0	0	0	0	0	0

Groups	Heifer ID	Virus isolations					VI Results
		Thymus	Spleen	Lung	Kidney	Buffy-coats	
Controls	1540	1	1	1	1	1	1
	1542	1	1	1	1	0	1
	1543	0	0	0	0	1	1
	1546	0	0	0	0	1	1
	1549	1	1	1	1	1	1
	1553	1	1	1	1	1	1
	1557	1	1	1	1	1	1
	1571	0	0	0	0	0	0
	1572	0	0	0	0	1	1
	1573	0	0	0	0	1	1
	1574	1	1	1	1	0	1
	1577	0	0	0	0	1	1
	1586	1	1	1	1	0	1
	1590	1	1	1	1	0	1
	1591	1	1	1	1	0	1
	1593	0	1	0	1	1	1
	1595	1	1	1	1	1	1
	1615	0	0	0	0	1	1

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against disease caused by IBR
Product Administration	Subcutaneous
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	March 29, 2004

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against abortions caused by IBR
Product Administration	Subcutaneous
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	June 27, 2005

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Rhinotracheitis Virus (IBR)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against infectious bovine rhinotracheitis 1 year after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>39 three-month-old male calves; 20 controls, 19 vaccinates</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with IBR 1 year (364 days) after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 14 days post-challenge for clinical signs of acute IBR. Nasal swabs were evaluated daily for 10 days post-challenge.</td></tr>
<tr><td>Results</td><td>Clinical Signs:
An affected calf was defined as displaying severe nasal or ocular discharge, cough, depressions, dyspnea, and/or nasal lesions on any post-challenge day.
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th></tr>
<tr><td>Vaccinates</td><td>19</td><td>1 (5%)</td></tr>
<tr><td>Controls</td><td>20</td><td>18 (90%)</td></tr>
</table>
Nasal Virus Shedding:
An affected calf was one in which nasal virus shedding was detected on any day post-challenge to evaluated duration of shedding
<table>
<tr><th>Group</th><th># of Animals</th><th># Affected</th></tr>
<tr><td>Vaccinates</td><td>19</td><td>19</td></tr>
<tr><td>Controls</td><td>20</td><td>20</td></tr>
</table>
* All control calves were still shedding virus on day 10 post-challenge.

Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>August 20, 2014</td></tr>
</table>

Clinical Observations Scoring

Nasal / Ocular Discharge
- 0 = Normal – dry and clean nose or eyes
- 1 = Mild – serous discharge
- 3 = Severe – mucopurulent discharge

Cough
- 0 = Normal – no cough
- 1 = Mild – occasional cough
- 3 = Severe – repeated cough

Attitude / Depression
- 0 = Normal – normal in activities
- 1 = Mild – head down, moves slowly, nearly normal appetite
- 3 = Severe – stands with difficulty, moves or responds to stimuli reluctantly, little interest in surroundings

Dyspnea
- 0 = Normal – breathing normally
- 1 = Mild – slight difficulty breathing, short and rapid breathing
- 3 = Severe – labored abdominal breathing, audible grunts or raspy breathing

Nasal Lesions
- 0 = Normal – no lesions on nasal mucosa
- 1 = Mild – white-colored lesions
- 3 = Severe – bloody or red colored lesions

Clinical Observations Post-Challenge

Group	ID	Day Post-Challenge													Affected*
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Vaccinates	505	ND1	0	ND1	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	ND1	ND1	ND1	No
	507	0	0	0	0	NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1	ND1	ND1	No
	508	0	0	0	0	NL1	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	0	ND1	0	No
	510	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1	0	0	No
	512	0	0	0	0	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	NL1	ND1	ND1	ND1	ND1	0	No
	513	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1,NL1	ND1	0	0	No
	516	0	0	ND1	0	NL1	NL1	NL1	NL1	NL1	NL1	0	0	NL1	0	0	0	No
	520	0	0	ND1	ND1	NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1,NL1	0	ND1	ND1	No
	522	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,C1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	0	No
	523	0	0	0	0	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	ND1	ND1	No
	524	0	0	0	0	ND1,NL1	ND1,D1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	No
	527	0	0	0	ND1	0	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	0	0	No
	532	0	0	0	0	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	0	0	ND1	No
	533	0	0	0	ND1	NL1	ND1,NL1	NL1	NL1	ND1,NL1	NL1	NL1	ND1,NL1	NL1	NL1	0	0	No
	536	0	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3	ND3	ND1	ND1	Yes
	540	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	0	0	0	0	ND1	ND1	No
	541	0	0	0	0	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	ND1	No
	542	0	0	0	0	NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	0	ND1	ND1	0	0	0	No
	543	0	0	0	0	NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	NL1	0	ND1	NL1	0	0	No
Controls	504	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,D3,NL1	ND3,D3,NL1	ND1,D1,NL1	ND1,NL1	ND3,NL1	ND3	ND1	ND1,NL1	Yes
	506	0	0	0	0	NL1	NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND1	ND1	ND1,NL1	Yes
	509	0	0	ND1	0	NL1	ND1,D1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND1,NL1	Yes
	511	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,D1,NL3	ND1,D3,NL1	ND1,NL1	ND1,D1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND1,NL1	Yes
	514	0	0	0	0	NL1	ND1,NL1	ND3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,D1,NL1	ND1,NL1	Yes
	515	0	0	0	0	NL1	NL1	ND1,NL1	ND3,NL1	ND1,NL1	ND1,D1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND1	Yes
	517	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	No
	518	0	0	0	0	NL1	NL1	ND1,NL1	ND3,NL3	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND3,A1, D3,NL1	ND1	Yes
	519	0	0	0	0	NL1	NL1	ND1,NL1	ND3,D1,NL3	ND3,D1,NL1	ND3,D1,NL1	ND3,NL1	ND3,D1,NL1	ND3,D1,NL1	ND3,D1,NL1	ND3,NL1	ND3,NL1	Yes
	521	0	0	0	0	NL1	ND1,D1,NL1	ND1,NL1	ND3,D1,NL1	ND3,D3,NL1	ND3,D3,NL1	ND3,D1,NL1	ND1,D1,NL3	ND3,NL3	ND3,D1,NL3	ND3,NL1	ND1,NL1	Yes
	525	0	0	0	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND1,NL3	ND1,NL1	ND3,NL1	Yes
	526	0	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	Yes
	528	ND1	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,D1,NL1	ND1,NL1	ND1,D3,NL1	ND3,D1,NL1	ND3,D1,NL1	ND1,D1,NL1	ND1,NL1	0	Yes
	529	0	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND3,D1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND1,NL1	Yes
	530	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND3,NL1	ND1,NL3	ND1,NL3	ND1,NL1	ND1,NL1	ND1	Yes
	531	ND1	0	ND1	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,D1,NL1	ND1,NL3	ND3,NL3	ND1,NL1	ND1,NL1	ND1	Yes
	534	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,D1,NL1	ND1,NL1	ND1,NL1	ND3,NL3	ND1,NL1	0	Yes
	535	0	0	0	0	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	ND1	No
	538	0	0	ND1	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND3,NL1	ND3,D1,NL1	ND3,D1,NL1	ND1,NL1	ND3,NL1	ND1	Yes
	539	0	0	0	NL1	NL1	NL1	ND1,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND1,NL1	ND3,D1,NL1	ND3,NL1	ND3,NL1	ND1,NL1	ND1,NL1	Yes

0 = Normal, ND = Nasal Discharge, C = Cough, A = Attitude (Depression), D = Dyspnea, NL = Nasal Lesions; Severity: 1 = Mild, 3 = Severe

*An affected calf is one with a severe clinical sign on any post-challenge day

000026

Nasal Swab Virus Shedding Results

			Nasal Virus Titer (Log_{10} $TCID_{50}$/mL) Day Post-Challenge											
Group	Calf ID	Vac.[1]	-1	0	1	2	3	4	5	6	7	8	9	10
Vaccinates	505	0	0	0	4.3	6.5	6.7	6.5	6.5	5.9	2.1	0	0	0
	507	0	0	0	4.7	7.3	7.7	6.7	6.7	6.5	2.1	0	0	0
	508	0	0	0	4.9	7.7	7.1	6.7	6.7	6.5	1.7	1.7	0	0
	510	0	0	0	4.9	7.1	6.7	6.3	6.9	5.7	0	0	0	0
	512	0	0	0	4.5	6.9	6.5	6.7	6.5	3.5	0	0	0	0
	513	0	0	0	4.5	5.7	6.9	6.5	6.9	6.9	4.9	2.5	0	0
	516	0	0	0	3.7	6.3	5.3	4.5	5.3	2.7	0	0	0	0
	520	0	0	0	4.5	6.3	6.3	5.7	5.7	5.1	3.5	0	0	0
	522	0	0	0	4.7	6.7	7.1	5.1	6.3	4.9	1.7	0	0	0
	523	0	0	0	5.1	7.7	8.1	6.3	6.7	5.7	1.7	0	0	0
	524	0	0	0	4.9	7.5	6.7	6.3	5.7	5.7	2.1	0	0	0
	527	0	0	0	4.9	7.1	7.3	6.7	6.1	5.7	3.5	0	0	0
	532	0	0	0	5.1	5.9	5.7	4.9	4.1	3.1	2.1	2.3	0	0
	533	0	0	0	5.3	7.9	7.1	6.1	6.7	5.9	2.1	0	0	0
	536	0	0	0	5.3	7.1	6.9	5.7	6.7	6.5	4.9	0	0	0
	537	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	540	0	0	0	6.1	6.7	6.7	4.7	5.7	3.5	0	0	0	0
	541	0	0	0	5.7	7.1	6.9	6.3	6.5	6.3	3.9	2.5	0	0
	542	0	0	0	5.1	5.9	5.9	4.9	5.9	4.3	2.7	0	0	0
	543	0	0	0	5.5	7.5	6.7	6.3	6.7	6.1	3.9	1.7	0	0
Controls	504	0	0	0	4.7	7.7	6.9	7.9	6.9	6.1	5.9	5.1	3.9	2.5
	506	0	0	0	4.7	7.5	6.9	6.7	7.1	5.9	6.7	4.7	4.1	2.9
	509	0	0	0	6.1	7.5	6.9	6.3	6.5	6.3	5.1	4.7	3.3	1.9
	511	0	0	0	4.7	7.3	7.7	6.5	6.1	6.1	5.5	4.5	4.3	2.5
	514	0	0	0	5.9	7.1	7.7	7.3	6.5	6.5	5.5	4.7	3.5	2.5
	515	0	0	0	5.1	7.3	7.3	7.5	7.3	6.5	5.3	4.1	3.1	1.9
	517	0	0	0	4.3	6.7	7.9	7.3	7.1	6.7	6.7	4.5	3.3	2.5
	518	0	0	0	4.9	7.7	7.3	7.3	6.7	6.1	6.3	5.3	3.5	2.3
	519	0	0	0	5.3	7.3	7.7	7.7	6.7	7.9	6.7	5.5	4.5	2.9
	521	0	0	0	5.3	7.7	7.9	6.9	6.5	6.3	6.5	5.9	3.7	2.9
	525	0	0	0	5.3	5.5	6.7	7.1	7.5	6.5	5.5	4.7	3.7	2.5
	526	0	0	0	5.1	6.9	7.3	6.9	6.3	7.3	5.9	5.1	4.3	2.5
	528	0	0	0	5.1	7.9	7.5	7.7	6.9	6.9	7.5	4.9	3.9	1.9
	529	0	0	0	5.3	7.3	6.9	7.1	6.3	5.5	6.3	5.1	3.9	2.1
	530	0	0	0	5.1	7.5	8.1	6.9	7.7	6.3	6.1	5.3	3.9	2.9
	531	0	0	0	5.1	6.9	7.3	7.9	7.9	6.9	6.5	4.5	3.5	2.1
	534	0	0	0	5.9	7.1	8.1	6.5	6.1	5.9	7.1	4.7	4.3	2.5
	535	0	0	0	5.1	7.5	7.9	7.7	7.1	6.7	5.9	5.1	3.1	1.9
	538	0	0	0	5.3	6.7	6.5	5.5	6.3	6.9	6.7	4.5	2.7	1.9
	539	0	0	0	6.3	7.3	7.9	6.3	7.1	6.3	5.3	3.5	2.5	1.7

[1] Prior to vaccination, Study day 0

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate efficacy against abortions caused by IBR at 217 days post vaccination.
Product Administration	Subcutaneous
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	March 16, 2006

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against M. haemolytica 16 weeks after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>34, 5-month-old calves; 17 controls (placebo), 17 vaccinates</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with M. haemolytica 113 days after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 7 days post-challenge for clinical signs of respiratory disease then tissues were examined.</td></tr>
<tr><td>Results</td><td><u>Lung Lesions</u>:
The percent of the affected lung tissue was determined, and a lung lesion score was calculated for each animal.
<table>
<tr><th>Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr>
<tr><td>Placebo</td><td>0</td><td>1</td><td>2</td><td>8</td><td>44</td></tr>
<tr><td>Vaccinates</td><td>0</td><td>0</td><td>0</td><td>1</td><td>19</td></tr>
</table>
Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 15, 2014</td></tr>
</table>

Table 1: Lung Lesion Scores

Calf ID	Treatment Group	Lung Lesion Score - 1	Lung Lesion Score - 2
569	Placebo	20.66	20.11
570	Placebo	1.44	2.33
571	Placebo	1.79	1.40
573	Placebo	7.61	7.62
576	Placebo	19.43	18.27
578	Placebo	1.69	2.48
579	Placebo	1.31	0.90
582	Placebo	3.97	4.11
585	Placebo	0.08	0.08
587	Placebo	9.16	5.82
588	Placebo	0.53	0.38
589	Placebo	0.25	0.24
594	Placebo	5.07	7.97
595	Placebo	18.17	20.57
596	Placebo	44.35	43.11
598	Placebo	1.08	0.47
600	Placebo	0.44	0.03
568	Vaccinate	0.50	0.55
572	Vaccinate	0.82	1.32
574	Vaccinate	19.71	18.91
575	Vaccinate	0.00	0.00
577	Vaccinate	0.00	0.00
580	Vaccinate	0.22	0.40
581	Vaccinate	0.16	0.00
583	Vaccinate	0.08	0.06
584	Vaccinate	0.62	2.60
586	Vaccinate	0.00	0.11
590	Vaccinate	0.00	0.00
591	Vaccinate	0.61	1.20
592	Vaccinate	0.82	2.12
593	Vaccinate	0.00	0.00
597	Vaccinate	0.00	0.43
599	Vaccinate	8.80	10.02
601	Vaccinate	0.17	0.00

Study Type	Efficacy
Pertaining to	*Mannheimia haemolytica*
Study Purpose	To demonstrate effectiveness against respiratory disease caused by *M. haemolytica*
Product Administration	Subcutaneous
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	March 17, 2004

Study Type	Efficacy
Pertaining to	Parainfluenza$_3$ Virus (PI3)
Study Purpose	To demonstrate effectiveness against shedding caused by PI3
Product Administration	Subcutaneous
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	April 12, 2005

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Pasteurella multocida</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against P. multocida 16 weeks after vaccination.</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>30, 3-month-old calves; 15 controls, 15 vaccinates</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with P. multocida 113 days after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 7 days post-challenge for respiratory disease. Lungs were evaluated 7 days following challenge.</td></tr>
<tr><td>Results</td><td><u>Lung Lesions</u>:
The percent of the lung tissue that was abnormal was determined, and a lung lesion score was calculated for each animal.
<table>
<tr><th>Group</th><th>N</th><th>Min</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max</th></tr>
<tr><td>Vaccinates</td><td>15</td><td>0.000</td><td>0.000</td><td>0.682</td><td>1.900</td><td>8.754</td></tr>
<tr><td>Control</td><td>15</td><td>0.000</td><td>2.765</td><td>3.887</td><td>11.522</td><td>32.211</td></tr>
</table>
Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 15, 2014</td></tr>
</table>

Table 1: Lung Lesion Scores

Calf ID	Treatment Group	Lung Lesion Score - 1	Lung Lesion Score - 2
132	Control	19.63	19.24
134	Control	3.35	3.15
135	Control	17.11	12.87
137	Control	0.00	0.00
140	Control	2.52	3.46
143	Control	0.00	0.00
148	Control	1.91	3.17
149	Control	2.08	2.41
150	Control	5.14	5.23
151	Control	18.74	16.02
152	Control	4.22	4.31
154	Control	7.45	8.66
155	Control	4.02	3.62
157	Control	3.53	4.24
161	Control	34.66	29.76
133	Vaccinate	0.51	0.86
136	Vaccinate	10.17	7.34
138	Vaccinate	0.00	0.00
139	Vaccinate	0.00	0.00
141	Vaccinate	0.00	0.29
142	Vaccinate	0.00	0.00
144	Vaccinate	7.44	7.33
145	Vaccinate	3.96	3.25
146	Vaccinate	0.31	0.51
147	Vaccinate	1.56	2.22
153	Vaccinate	0.00	0.00
156	Vaccinate	1.95	1.87
158	Vaccinate	0.96	0.94
159	Vaccinate	1.25	1.25
160	Vaccinate	0.00	0.00

Study Type	Efficacy
Pertaining to	*Pasteurella multocida*
Study Purpose	To demonstrate effectiveness against respiratory disease caused by *P. multocida*
Product Administration	Subcutaneous
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	March 17, 2004

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	To demonstrate effectiveness against BRSV
Product Administration	Subcutaneous
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	June 3, 2004

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety in pregnant animals under field conditions when cows or heifers are vaccinated prior to breeding, within the previous 12 months, with a modified live Infectious Bovine Rhinotracheitis Virus (IBRV) and Bovine Viral Diarrhea Virus (BVDV) product
Product Administration	Two doses, administered subcutaneously. First vaccination given 14 to 60 days prior to breeding. Second vaccination given during a specified trimester of pregnancy.
Study Animals	1st Trimester Study: 468 pregnant heifers (52 – 86 days pregnant) 2 years of age and older. 2nd Trimester Study: 461 pregnant heifers (100 – 180 days pregnant) 2 – 14 years of age. 3rd Trimester Study: 440 pregnant heifers (≥190 days pregnant) 2 years of age and older.
Challenge Description	Not applicable
Interval observed after challenge	All cows were observed from pre-breeding vaccination through calving.
Results	Summary of the results listed in the table below
USDA Approval Date	May 9, 2013

Summary of the results as follows:

Trimester	Group	No. of Cows		Fetal Loss (%) related to vaccination	Fetal Loss (%) unrelated to vaccination as affirmed by licensee
		Entered	Removed*		
1st	Vaccinates	235	4	1 (0.4 %)	3 (1.3%)
	Controls	233	7	2 (0.9%)	2 (0.9%)
2nd	Vaccinates	231	2	1 (0.4%)	6 (2.5%)
	Controls	230	0	1 (0.4%)	2 (0.8%)
3rd	Vaccinates	216	1	0 (0%)	8 (3.7%)
	Controls	224	2	1 (0.5%)	5 (2.2%)

*Number of cows removed from the study results due to death serious illness considered unrelated to vaccination as affirmed by licensee

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	Subcutaneous
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	May 31, 2005