Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1181.28
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovi-Shield Gold FP 5 - No distributor specified Bovi-Shield Gold FP 5 - Zoetis Mexico Bovi-Shield Gold FP 5 - Zoetis South Africa Ltd
Date of Compilation Summary	February 13, 2023

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD) Type 1
Study Purpose	To demonstrate fetal protection against persistent infection of calves
Product Administration	One dose administered subcutaneously (SC) or intramuscularly (IM) 35 days prior to breeding to heifers
Study Animals	20 SC vaccinated, 20 IM vaccinated, and 10 control heifers, 13–17 months of age, seronegative to BVD1 and BVD2 (serum neutralizing antibody titers < 2) and negative for BVD persistent infection (ear notch immunohistochemistry).
Challenge Description	BVD1b (non-cytopathic) seeder calf challenge 124-138 days post vaccination
Interval observed after challenge	Dams were observed daily up to 83 days after challenge. Fetuses were assessed for persistent infection on or after 150 days of gestation
Results	Fetuses were considered persistently infected if the they were seropositive for BVD (serum neutralizing antibody titers ≥ 3) and/or tissues examined (fetal thymus, spleen, liver, lung, kidney, ear notch samples) were positive for BVD antigen (immunohistochemistry, virus isolation, and/or ELISA). Aborted fetuses were considered persistently infected. Number of BVD persistently infected calves: Controls: 10/10 Vaccinates (SC): 3/16* Vaccinates (IM): 3/20 *Fetuses of four SC vaccinated dams were removed from the study due to being assessed for persistent infection before 150 days of gestation.
USDA Approval Date	03/07/2019

BVD Persistent Infection of Fetus Summary

Treatment Group	Animal Id.	Abortion	Fetal Serum NAb Titer		Fetal Tissue BVD	Fetal Tissue BVD Immunohistochemistry						Fetal Tissue BVD Viral Isolation						Persistent Infection
			BVD1	BVD2	Ear	Ear	Kidney	Liver	Lung	Spleen	Thymus	Serum	Kidney	Liver	Lung	Spleen	Thymus	
Con	15	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	25	No	<3	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	34	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	37	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	47	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	53	Yes	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Yes
Con	56	Yes	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Yes
Con	94	No	<2	<3	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	104	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
Con	109	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
SC	6	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	17	No	<2	<3	-	-	-	-	-	-	-	-	+	+	-	-	-	Yes
SC	23	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	52	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	55	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	59	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	62	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	68	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	70	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	75	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	78	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
SC	81	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	83	No	1218	3	-	-	-	-	-	-	-	-	-	-	-	-	-	Yes
SC	86	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	98	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
SC	110	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No

Con: Control; Nab: neutralizing antibody; +: fetal tissue positive for BVD; -: fetal tissue negative for BVD

Persistent Infection

Yes: positive for BVD persistent infection because at least one fetal tissue was positive for BVD by ELISA, immunohistochemistry, or viral isolation, or due to abortion of the dam

No: negative for BVD persistent infection because all fetal tissues were negative

Treatment Group	Animal Id.	Abortion	Fetal Serum NAb Titer		Fetal Tissue BVD	Fetal Tissue BVD Immunohistochemistry						Fetal Tissue BVD Viral Isolation						Persistent Infection
			BVD1	BVD2	Ear	Ear	Kidney	Liver	Lung	Spleen	Thymus	Serum	Kidney	Liver	Lung	Spleen	Thymus	
IM	10	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	14	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	19	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	29	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	36	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
IM	41	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	43	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	44	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	45	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	51	No	<2	<2	+	+	+	+	+	+	+	+	+	+	+	+	+	Yes
IM	54	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	63	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	64	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	66	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	72	No	<2	<3	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	76	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	84	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	90	No	<2	<3	-	-	-	-	-	-	-	+	-	-	-	-	-	Yes
IM	99	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No
IM	106	No	<2	<2	-	-	-	-	-	-	-	-	-	-	-	-	-	No

Con: Control; Nab: neutralizing antibody; +: fetal tissue positive for BVD; -: fetal tissue negative for BVD

Persistent Infection

Yes: positive for BVD persistent infection because at least one fetal tissue was positive for BVD by ELISA, immunohistochemistry, or viral isolation, or due to abortion of the dam

No: negative for BVD persistent infection because all fetal tissues were negative

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus, type 1 (BVDV1)
Study Purpose	Demonstrate efficacious against persistently infected calves caused by BVDV1
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV1 strain 816317(b)
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	02/06/2002

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus, type 1 (BVDV1)
Study Purpose	Demonstrate 1-year duration of immunity against persistently infected calves caused by BVDV1
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV1 strain 816317(b)
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	07/08/2005

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 Virus Diarrhea Virus, Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV1
Product Administration	One dose administered to heifers subcutaneously 35 days prior to breeding
Study Animals	20 vaccinated and 19 control heifers, 16-18 months of age at vaccination. Seronegative titers (< 2) to BVDV1 and BVDV2 at vaccination
Challenge Description	Non-cytopathic BVDV1b isolate 765313263 administered 230 days after vaccination (169-194 days of gestation)
Interval observed after challenge	Fetuses examined 50 days following challenge
Results	A fetus was considered affected by the challenge if it displayed a BVDV seropositive titer (≥ 2) from serum samples or BVDV virus was isolated from at least one tissue sample. Fetuses negative for both were considered protected from fetal infection. 19/19 control heifers and 6/20 vaccinates produced calves with fetal infection. Summary of individual fetal BVDV1 serum neutralizing antibody titers and virus isolation results[1]. Raw data is found in Table 1.

Control ID	Virus	Fetal Antibody	Vaccinates ID	Virus	Fetal Antibody
62	-	724	61	-	<2
65	-	2896	69	-	<2
66[2]	-	362	75	-	<2
66[2]	-	256	76[3]	-	45
70	-	2896	81	-	<2
71	-	2048	82	-	<2
78	-	181	89	-	724
80	+	<2	91	-	<2
84	-	512	94	-	<2
86	-	2435	98	-	256
87	+	<2	100	-	1722
88	-	362	101	-	724
92	-	1024	104	-	<2
93	-	1024	110	-	<2
103[3]	+	<2	111	-	<2
105	-	91	112	-	<2
108	-	58386	114	-	<2
109	+	<2	116	-	<2
115	-	1218	118	-	91
117	-	1722	119	-	<2

[1] + = positive for virus isolation; - = negative for virus isolation.
[2] Pregnant animal 66 had twins and the results from both fetuses are included.

	[3]The fetuses from animals 76 and 103 were aborted. The tissues for 76 were submitted for immunohistochemical analysis. Fetus 76's tissues were negative for the presence of BVDV antigen.
USDA Approval Date	03/18/2015

Table 1: Individual fetal BVDV serum neutralizing antibody titers and virus isolation results[1].

Trt	Animal	BVDV 1 SN Titers	BVDV 2 SN Titers	Blood VI	Liver VI	Kidney VI	Spleen VI	Thymus VI
T01	62	724	23	N	N	N	N	N
	65	2896	16	N	N	N	N	N
	66[2]	362	32	N	N	N	N	N
	66[2]	256	27	N	N	N	N	N
	70	2896	32	N	N	N	N	N
	71	2048	19	N	N	N	N	N
	78	181	19	N	N	N	N	N
	80	<2	<2	Y	Y	Y	Y	Y
	84	512	16	N	N	N	N	N
	86	2435	54	N	N	N	N	Y
	87	<2	<2	Y	Y	Y	Y	Y
	88	362	64	N	N	N	N	N
	92	1024	91	N	N	N	N	N
	93	1024	27	N	N	N	N	N
	103[3]	<2	<2	N	Y	Y	Y	N
	105	91	108	N	N	N	N	N
	108	58386	45	N	N	N	N	N
	109	<2	<2	N	Y	Y	Y	Y
	115	1218	45	N	N	N	N	N
	117	1722	108	N	N	N	N	N
T02	61	<2	<2	N	N	N	N	N
	69	<2	<2	N	N	N	N	N
	75	<2	<2	N	N	N	N	N
	76[3]	<45	<45	N	N	N	N	N
	81	<2	<2	N	N	N	N	N
	82	<2	<2	N	N	N	N	N
	89	724	32	N	N	N	N	N
	91	<2	<2	N	N	N	N	N
	94	<2	<2	N	N	N	N	N
	98	256	181	N	N	N	N	N
	100	1722	128	N	N	N	N	N
	101	724	76	N	N	N	N	N
	104	<2	<2	N	N	N	N	N
	110	<2	<2	N	N	N	N	N
	111	<2	<2	N	N	N	N	N
	112	<2	<2	N	N	N	N	N
	114	<2	<2	N	N	N	N	N
	116	<2	<2	N	N	N	N	N
	118	91	32	N	N	N	N	N
	119	<2	<2	N	N	N	N	N

[1]VI = Virus Isolation; Y = yes or positive for virus isolation; N = no or negative for virus isolation.
SN = Serum Neutralization antibody titer; ≥ 2 is considered positive

[2] Heifer 66 had twins and the results from both fetuses are included.

[3] The fetuses from heifers 76 and 103 were aborted. The tissues for 76 were submitted for immunohistochemical analysis. Fetus 76's tissues were negative for the presence of BVDV antigen.

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus, type 2 (BVDV2)
Study Purpose	Demonstrate efficacious against persistently infected calves caused by BVDV2
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV2a strain 94B-5359a
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	08/06/2004

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus, type 2 (BVDV2)
Study Purpose	Demonstrate efficacy against testicular infection 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	12/01/2003

Study Type	Efficacy
Pertaining to	Bovine viral diarrhea virus, type 2 (BVDV2)
Study Purpose	Demonstrate 1-year duration of immunity against persistently infected calves caused by BVDV2
Product Administration	
Study Animals	
Challenge Description	Non-cytopathic BVDV2a strain 94B-5359a
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	07/08/2005

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 Virus Diarrhea Virus type 2 (BVDV2)
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV2
Product Administration	One dose administered subcutaneously approximately 1 month prior to breeding in heifers
Study Animals	20 vaccinated and 20 control heifers 16-18 months of age at vaccination. Seronegative to BVDV1 and BVDV 2 (titer <2)
Challenge Description	Non-cytopathic BVDV2a strain 94B-5359a (non-cytopathic) administered 230 days after vaccination (~174-194 days of gestation)
Interval observed after challenge	Fetuses examined 49 days following challenge
Results	A fetus was considered affected by the challenge if the calf had a BVDV serum neutralizing antibody titer ≥2 OR BVDV could be isolated from at least one tissue sample. Fetuses negative for both were considered protected from fetal infection. 20/20 controls and 1/20 vaccinates produced calves with fetal infection. Summary of individual fetal BVDV2 serum neutralizing antibody titers and virus isolation results[1]. Raw Data is found in Table 1.

Control ID	Virus Isolation	Fetal Antibody	Vaccinate ID	Virus	Fetal Antibody
1	+	3	4	-	<2
2	-	861	9	-	<2
7	-	16384	13	-	<2
8	+	11	14	-	<2
16	-	1218	18	-	<2
20	-	2435	19	-	<2
21	-	1448	22	-	<2
30*	-	2048	25	-	<2
36	+	2	26	-	<2
37	+	3	27**	-	<2
39	-	1024	27	-	<2
42	-	2435	28	-	<2
43	+	<2	29	-	<2
44	+	8	31	-	<2
47	-	2896	33	-	<2
49	+	<2	35	+	<2
50	+	<2	40	-	<2
52	+	3	41	-	<2
54	-	2048	48	-	<2
55	+	7	59	-	<2
			60	-	<2

[1] Y = Yes or positive; N = No or negative for Virus Isolation.

	*Fetus was aborted. The tissues were submitted for immunohistochemistry analysis and were positive for the presence of BVDV antigen. **This animal had twins, both were negative for serum and tissue samples.
USDA Approval Date	03/18/2015

Table 1: Individual fetal BVDV serum neutralizing antibody titers and virus isolation results*.

Trt	Animal	BVDV 1 SN Titers	BVDV 2 SN Titers	Blood VI	Kidney VI	Liver VI	Spleen VI	Thymus VI
T01	1	<2	3	Y	Y	Y	Y	Y
	2	6	861	N	N	N	N	N
	7	64	16384	N	N	N	N	N
	8	<2	11	Y	Y	Y	Y	Y
	16	215	1218	N	N	N	N	N
	20	108	2435	N	N	N	N	N
	21	128	1448	N	N	N	N	N
	30**	256	2048	N	N	N	N	N
	36	<2	2	Y	Y	Y	Y	Y
	37	<2	3	Y	Y	Y	Y	Y
	39	45	1024	N	N	N	N	N
	42	64	2435	N	N	N	N	N
	43	<2	<2	Y	Y	Y	Y	Y
	44	2	8	Y	Y	Y	Y	Y
	47	108	2896	N	N	N	N	N
	49	<2	<2	Y	Y	Y	Y	Y
	50	<2	<2	Y	Y	Y	Y	Y
	52	<2	3	Y	Y	Y	Y	Y
	54	362	2048	N	N	N	N	N
	55	<2	7	Y	Y	Y	Y	Y
T02	4	<2	<2	N	N	N	N	N
	9	<2	<2	N	N	N	N	N
	13	<2	<2	N	N	N	N	N
	14	<2	<2	N	N	N	N	N
	18	<2	<2	N	N	N	N	N
	19	<2	<2	N	N	N	N	N
	22	<2	<2	N	N	N	N	N
	25	<2	<2	N	N	N	N	N
	26	<2	<2	N	N	N	N	N
	27***	<2	<2	N	N	N	N	N
	27***	<2	<2	N	N	N	N	N
	28	<2	<2	N	N	N	N	N
	29	<2	<2	N	N	N	N	N
	31	<2	<2	N	N	N	N	N
	33	<2	<2	N	N	N	N	N
	35	<2	<2	Y	Y	Y	Y	Y
	40	<2	<2	N	N	N	N	N
	41	<2	<2	N	N	N	N	N
	48	<2	<2	N	N	N	N	N
	59	<2	<2	N	N	N	N	N
	60	<2	<2	N	N	N	N	N

*VI = virus isolation; Y = yes or positive; N = no or negative for virus isolation.
SN = Serum Neutralization antibody titer; ≥2 is positive
** The fetus from heifer 30 was aborted. The tissues were submitted for immunohistochemical analysis and were positive for the presence of BVDV antigen.
***Animal 27 had twins.

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus, type 2 (BVDV2)
Study Purpose	Demonstrate efficacious against persistently infected calves caused by BVDV2
Product Administration	
Study Animals	Pre-breeding heifers seronegative to BVDV1 and BVDV2
Challenge Description	Non-cytopathic BVDV2a strain 94B-5359a
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	02/06/2002

<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 efficacy against respiratory disease caused by BVDV2 in calves.</td></tr>
<tr><td>Product Administration</td><td>One dose was administered intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>Twenty-nine, 3-4-month-old beef calves, 19 vaccinates and 10 controls. Seronegative (<1:2) to BVDV1 and BVDV2 at vaccination.</td></tr>
<tr><td>Challenge Description</td><td>BVDV2a Strain 24515 (non-cytopathic) administered 35 days following vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>Viremia was defined as at least one occasion where virus was isolated post-challenge. Leukopenia was defined as ≥ 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.</td></tr>
<tr><td>USDA Approval Date</td><td>7/17/2008</td></tr>
</table>

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
	54	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Vaccinates	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
	54	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
Vaccinates	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	Herpesvirus, bovine (IBR)
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	Infectious bovine rhinotracheitis (IBR)
Study Purpose	Demonstrate efficacy against abortion caused by infectious bovine rhinotracheitis
Product Administration	One dose administered intramuscularly (IM)
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	February 6, 2002

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	Herpesvirus, bovine (IBR)
Study Purpose	Demonstrate a 1 year duration of immunity against abortion caused by infectious bovine rhinotracheitis
Product Administration	
Study Animals	Pre-breeding heifers
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	07/08/2005

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	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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Parainfluenza type 3 Virus</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against virulent bovine parainfluenza type 3 virus (PI3) when challenged 28 days post-vaccination.</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Six- to 8-month-old Holstein calves and seronegative to PI3 (SN antibody titer ≤ 2). Twelve placebo controls and 24 vaccinates.</td></tr>
<tr><td>Challenge Description</td><td>PI3 challenge on day 28.</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>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>
Serology outcome
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.</td></tr>
<tr><td>USDA Approval Date</td><td>01/23/2008</td></tr>
</table>

PI3 virus isolation (log_{10} $TCID_{50}$) 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

[1]A virus titer of $\leq$1.8 $\log_{10}$ $TCID_{50}$ 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

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Parainfluenza Type 3</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against virulent bovine parainfluenza type 3 virus (PI3) when challenged 29 days post-vaccination</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>25 vaccinated and 11 control male holstein calves, 10.5-11 months of age and seronegative to PI3 (serum neutralizing antibody titers ≤1:2).</td></tr>
<tr><td>Challenge Description</td><td>PI3 challenge on Day 29.</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>Duration of shedding in days:

<table>
<tr><th></th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></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.</td></tr>
<tr><td>USDA Approval Date</td><td>07/17/2008</td></tr>
</table>

PI3 virus isolation (log_{10} $TCID_{50}$), 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 $\log_{10}$ $TCID_{50}$ is considered negative.
[2]Data 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

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Respiratory Syncytial Virus (BRSV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate effectiveness against respiratory disease caused by BRSV.</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly (IM) or subcutaneously (SC).</td></tr>
<tr><td>Study Animals</td><td>Sixteen- to 40-day-old Holstein calves, seronegative to BRSV. 14 controls, 20 IM vaccinates and 18 SC vaccinates.</td></tr>
<tr><td>Challenge Description</td><td>BRSV challenge 25 days after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Mortality and lungs (at the time of mortality or at 8 days post-challenge) were evaluated.</td></tr>
<tr><td>Results</td><td>The primary outcome was based on lung lesions. The percent of lung that was abnormal (consolidated/lesion) was calculated for every animal (see individual data).

Percent of Lung Lesions (5-number summary)
<table>
<tr><th rowspan="2">Treatment</th><th colspan="5">Percent (%) Total Lung with Lesions</th></tr>
<tr><th>Min.</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max.</th></tr>
<tr><td>Controls</td><td>14.7</td><td>25</td><td>50.3</td><td>66.5</td><td>81.2</td></tr>
<tr><td>IM Vaccinates</td><td>3.8</td><td>11.9</td><td>18.2</td><td>23.2</td><td>57.3</td></tr>
<tr><td>SC Vaccinates</td><td>14.5</td><td>16.3</td><td>23.8</td><td>45.1</td><td>82.3</td></tr>
</table>

Mortality was evaluated as supportive data.
Post-Challenge Mortality Rates
<table>
<tr><th>Treatment</th><th>Mortality</th><th>Percent</th></tr>
<tr><td>Controls</td><td>9/14</td><td>64.3 %</td></tr>
<tr><td>IM Vaccinates</td><td>1/19</td><td>5.3 %</td></tr>
<tr><td>SC Vaccinates</td><td>3/18</td><td>16.7 %</td></tr>
</table>

Please see attached page for individual raw data.</td></tr>
<tr><td>USDA Approval Date</td><td>07/17/2008</td></tr>
</table>

Individual Mortality and Lung Lesion Results:

Treatment	Animal ID	Mortality	Percent of Lung Lesions
Controls	03	Yes	66.53
	09	Yes	70.48
	13	Yes	81.18
	14	No	14.65
	15	Yes	66.25
	16	Yes	74.41
	40	Yes	31.75
	42	No	61.33
	43	No	46.45
	44	No	25.00
	53	Yes	54.10
	56	No	22.10
	59	Yes	16.30
	61	Yes	39.84
IM Vaccinates	01	No	20.08
	04	No	16.28
	05	No	22.85
	07	No	6.15
	12	No	15.22
	19	No	4.63
	21	No	10.33
	35	No	16.24
	36	No	57.25
	38	No	13.375
	41	No	23.60
	45	No	20.08
	46	-*	3.76
	48	No	47.80
	50	No	9.43
	55	No	20.18
	58	No	24.90
	60	No	14.04
	63	No	54.70
	64	No	21.19

*: Animal died from severe diarrhea and was removed from the mortality analysis.

Treatment	Animal ID	Mortality	Percent of Lung Lesions
SC Vaccinates	02	Yes	45.05
	06	Yes	46.60
	08	No	14.49
	10	No	14.65
	11	Yes	82.34
	17	No	15.80
	20	No	38.28
	33	No	22.95
	34	No	34.95
	37	No	65.02
	39	No	34.15
	47	No	14.50
	49	No	46.03
	51	No	21.90
	52	No	19.85
	54	No	20.53
	57	No	16.30
	62	No	24.55

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>
</table>

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety in pregnant cattle and calves nursing pregnant cattle under field condition
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after administration	
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	07/16/2003

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety in pregnant cattle and calves nursing pregnant cattle under field condition
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after administration	
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	07/16/2003

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety in pregnant cattle and calves nursing pregnant cattle under field condition
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after administration	
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	07/16/2003