



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1151.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Express FP 3 - No distributor specified
Date of Compilation Summary	December 02, 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 (BVD)
Study Purpose	Demonstration of efficacy against BVD Type 1 (respiratory disease)
Product Administration	
Study Animals	Bovine
Challenge Description	BVD Type 1 isolate 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	November 9, 1998

Study Type	Efficacy													
Pertaining to	Bovine Virus Diarrhea Type 1 (BVD1)													
Study Purpose	Demonstration of 12 month duration of immunity against BVD1 (respiratory and reproductive)													
Product Administration	One dose, subcutaneously													
Study Animals	Heifers (22 Vaccinates and 23 Controls), 12-15 months of age													
Challenge Description	Challenged with noncytopathic BVD1b BJ strain, 12 months (368 days) after vaccination and approximately 93 days of gestation.													
Interval observed after challenge	Observed for 14 days after challenge. Blood collected on days 0, 2, 4, 6, 8, 10, 12 and 14 after challenge to evaluate viremia and leukopenia. Fetuses collected on day 72 after challenge.													
Results	<p>Results of the study are summarized as follows:</p> <p>Blood was evaluated for viremia (the presence of virus) and leukopenia (at least one white blood cell count no greater than 40% of pre-challenge baseline count).</p> <p>Positive for Viremia and Leukopenia:</p> <table border="1"> <thead> <tr> <th></th> <th>Viremia</th> <th>Leukopenia</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0/22 (0%)</td> <td>8/22 (36%)</td> </tr> <tr> <td>Controls</td> <td>19/23 (83%)</td> <td>21/23 (91%)</td> </tr> </tbody> </table> <p>Calves (fetuses) were considered positive for persistent BVD infection if at least one fetal tissue was positive or if heifers were open when the fetuses were harvested. The fetal tissues spleen, thymus, heart blood, and cerebellum were evaluated for the presence of BVD1 by virus isolation.</p> <p>Positive for BVD Persistent Infection:</p> <table border="1"> <tbody> <tr> <td>Vaccinates</td> <td>1/22 (5%)</td> </tr> <tr> <td>Controls</td> <td>20/23 (87%)</td> </tr> </tbody> </table> <p>See tables on the following pages for data.</p>		Viremia	Leukopenia	Vaccinates	0/22 (0%)	8/22 (36%)	Controls	19/23 (83%)	21/23 (91%)	Vaccinates	1/22 (5%)	Controls	20/23 (87%)
	Viremia	Leukopenia												
Vaccinates	0/22 (0%)	8/22 (36%)												
Controls	19/23 (83%)	21/23 (91%)												
Vaccinates	1/22 (5%)													
Controls	20/23 (87%)													
USDA Approval Date	October 3, 2011													

Viremia

Vaccinates (22 bovine)

Animal ID	Days Post-Challenge							
	0	2	4	6	8	10	12	14
5	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-
64	-	-	-	-	-	-	-	-
77	-	-	-	-	-	-	-	-
92	-	-	-	-	-	-	-	-
120	-	-	-	-	-	-	-	-
125	-	-	-	-	-	-	-	-
149	-	-	-	-	-	-	-	-
152	-	-	-	-	-	-	-	-
156	-	-	-	-	-	-	-	-
181	-	-	-	-	-	-	-	-
185	-	-	-	-	-	-	-	-
201	-	-	-	-	-	-	-	-
223	-	-	-	-	-	-	-	-
250	-	-	-	-	-	-	-	-
260	-	-	-	-	-	-	-	-
263	-	-	-	-	-	-	-	-
277	-	-	-	-	-	-	-	-
300	-	-	-	-	-	-	-	-

Controls (23 bovine)

Animal ID	Days Post-Challenge							
	0	2	4	6	8	10	12	14
17	-	-	-	-	+	-	-	-
22	-	-	-	-	-	-	-	-
51	-	-	-	-	+	-	-	-
53	-	-	-	-	-	-	-	-
58	-	-	-	-	+	-	-	-
66	-	-	-	+	-	-	-	-
94	-	-	-	-	+	+	-	-
103	-	-	-	-	+	-	-	-
111	-	-	-	+	+	-	-	-
134	-	-	-	-	+	-	-	-
135	-	-	-	+	-	-	-	-
136	-	-	-	-	+	-	-	-
141	-	-	-	-	-	-	-	-
179	-	-	-	+	+	-	-	-
198	-	-	-	-	+	-	-	-
225	-	-	-	+	+	-	-	-
230	-	-	-	-	+	-	-	-
236	-	-	-	-	+	-	-	-
241	-	-	-	+	+	-	-	-
243	-	-	+	+	+	-	-	-
259	-	-	-	-	+	-	-	-
262	-	-	-	-	+	-	-	-
283	-	-	-	-	-	-	-	-

+ = positive for virus (highlighted yellow)
 - = negative for virus

Leukopenia in Vaccinates (22 bovine)

Animal ID	White Blood Cell Count per each Day Post-Challenge									Overall Result
	Baseline (-2)	0	2	4	6	8	10	12	14	
5	6.8	7.5	6	8.9	7	10	6.6	7.7	6.7	-
11	8.8	8.1	4.9	7.3	5.4	5.6	4.9	4	5.9	+
29	7.2	6.2	3.6	4.6	5	4.5	4.7	5	4.3	+
37	8.9	7.3	6.2	6.9	6.1	4.4	7.1	4.1	3.9	+
56	6.5	5.3	6.4	4.9	5	5.3	6.8	4.8	5.1	-
64	8.8	7	7.2	8.9	8.1	6.7	5.3	7.4	6.6	-
77	5	7.1	3.3	5	5.9	5.8	3.1	3.9	2.7	+
92	6	7.1	4.6	4	5.7	5.6	4.8	5.2	4.4	-
120	8.1	4.8	5.6	7.5	5	4.9	4.7	4.7	6.9	+
125	4.6	7.8	8.3	5.3	5.3	5.7	4.8	5.1	4.1	-
149	9.1	8.3	7.4	6.7	6.6	6.2	8.4	5.9	5.5	-
152	9.4	12	8.6	5.4	6.9	6.8	5.3	7.9	7.8	+
156	8.1	10	7.3	7.1	7.3	7.9	6.6	7.1	6.6	-
181	6.8	5.7	4.9	4.6	4.2	4.5	6	3.9	2.8	+
185	7.2	4.9	5.8	5.4	7.7	7.8	5.8	5.6	5.1	-
201	7.2	8.2	6.2	5.6	6.2	6.5	5.9	6.3	8.1	-
223	7.8	7.8	8	7.6	6	5.1	5.7	5	6	-
250	7.9	6	6.2	5	5	8.5	5.6	6	5.7	-
260	9.3	6.3	5.9	6.1	7.3	5.9	6.1	6.2	6.1	-
263	7	9.7	7.2	6.8	7.6	7	7.7	6.3	8.3	-
277	11.3	5.6	6	5.9	4.9	4.5	6.8	4.1	4.1	+
300	6.2	7.2	5.2	4.4	6.3	6.7	5.5	6.5	6.9	-

White Blood Cell Count:

- Numerical values = white blood cell count in thousands of cells per cubic millimeter of blood (i.e. 6.8 equals 6,800 cells/mL³)

Overall Result:

- + = positive for leukopenia at least one day (highlighted yellow)
- = negative for leukopenia on every day

Leukopenia in Controls (23 bovine)

Animal ID	White Blood Cell Count per each Day Post-Challenge									Overall Result
	Baseline (-2)	0	2	4	6	8	10	12	14	
17	7.4	7.6	5.3	2.4	3.5	2.7	6.6	8.2	5.7	+
22	7.2	7.3	6.4	2.5	3.6	3.2	5.1	5.2	5.9	+
51	4	6.6	5.4	2.7	4.1	4	4.5	4.8	3.9	-
53	7.3	8.1	6.9	2.5	3.2	5.9	8.8	4.2	4.5	+
58	11.5	10.2	8	4	4.7	4.7	9.5	5	7.5	+
66	8.3	6.2	3.5	3.7	2.7	5	6.5	3.8	5.6	+
94	8.3	6.8	6.7	4.5	6.2	6.3	9.5	9.4	8.4	+
103	12.5	7.2	5.8	3.5	4.3	4.9	5	4.2	6.6	+
111	8.9	5.6	6.8	3.6	5.5	5.6	6.8	6.5	3.8	+
134	8.6	9.6	6.1	4.5	3.8	6.3	5.7	7.4	11.4	+
135	6.4	6.1	5.8	3.4	4	3.7	3.9	5.3	6.7	+
136	7.1	6.4	5.9	3.4	4.8	5.5	6.8	7.4	7.1	+
141	19.3	16	10.5	4.9	5.8	6.7	5.9	6.7	6.3	+
179	5.5	6.8	6.7	2	2.5	5	2.9	3.2	5.8	+
198	12.8	9	8.1	2.6	2.8	3.5	4.5	4.4	4.6	+
225	8.3	8.4	9.6	4.7	4.4	5.3	4.3	3.6	5.1	+
230	7.7	9.2	7.9	3.5	4.9	6.4	5.9	6	8	+
236	11.4	11.8	9.2	3.6	4.4	5.5	7.8	7.2	5.5	+
241	9.4	7.7	5.9	3.2	4	5.7	8.7	5.4	6.4	+
243	5	5	5.7	2.9	3.4	8.1	3.5	3.4	5.4	+
259	5.2	6.4	8.4	3.7	5.6	10.1	8.5	8.9	6.8	-
262	8.6	8.1	7.7	3.7	6.3	6.8	3.9	8.5	4.8	+
283	4.8	5.5	5.5	1.5	3	4.6	2.9	2.8	2.5	+

White Blood Cell Count:

- Numerical values = white blood cell count in thousands of cells per cubic millimeter of blood (i.e. 6.8 equals 6,800 cells/mL³)

Overall Result:

- + = positive for leukopenia at least one day (highlighted yellow)
- = negative for leukopenia on every day

Persistent Infection of Calves

Vaccinates (22 bovine)

Animal ID	Result	Virus Isolation: BVD Type 1			
		Spleen	Thymus	Heart Blood	Brain
5	Negative	-	-	-	-
11	Negative	-	-	-	-
29	Negative	-	-	-	-
37	Negative	-	-	-	-
56	Negative	-	-	-	-
64	Negative	-	-	-	-
77	Negative	-	-	-	-
92	Negative	-	-	-	-
120	Negative	-	-	-	-
125	Negative	-	-	-	-
149	Negative	-	-	-	-
152	Negative	-	-	-	-
156	Negative	-	-	-	-
181	Positive	NA	NA	NA	NA
185	Negative	-	-	-	-
201	Negative	-	-	-	-
223	Negative	-	-	-	-
250	Negative	-	-	-	-
260	Negative	-	-	-	-
263	Negative	-	-	-	-
277	Negative	-	-	-	-
300	Negative	-	-	-	-

Controls (23 bovine)

Animal ID	Result	Virus Isolation: BVD Type 1			
		Spleen	Thymus	Heart Blood	Brain
17	Positive	+	+	+	+
22	Negative	-	-	-	-
51	Positive	+	+	+	+
53	Negative	-	-	-	-
58	Positive	+	+	+	+
66	Positive	+	+	+	+
94	Positive	+	+	+	+
103	Positive	-	+	+	+
111	Positive	+	+	+	+
134	Positive	+	+	+	+
135	Positive	NA	NA	NA	NA
136	Positive	+	+	+	+
141	Positive	NA	NA	NA	NA
179	Positive	+	+	+	+
198	Negative	-	-	-	-
225	Positive	NA	NA	NA	NA
230	Positive	NA	NA	NA	NA
236	Positive	+	+	+	+
241	Positive	-	+	+	+
243	Positive	+	+	+	+
259	Positive	+	+	+	+
262	Positive	NA	NA	NA	NA
283	Positive	+	+	+	+

Result:

Positive = positive for BVD persistent infection because at least one fetal tissue was positive, or heifer was open
 Negative = negative for BVD persistent infection because all fetal tissues were negative

Virus Isolation:

+ = fetal tissue positive for BVD1 by virus isolation
 - = fetal tissue negative for BVD1 by virus isolation
 NA = not applicable because heifer was open

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD)
Study Purpose	Demonstration of efficacy against BVD Type 2 (respiratory disease)
Product Administration	
Study Animals	Bovine
Challenge Description	BVD Type 2a isolate BVD 890
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	November 9, 1998

Study Type	Efficacy													
Pertaining to	Bovine Virus Diarrhea Type 2 (BVD2)													
Study Purpose	Demonstration of 12 month duration of immunity against BVD2 (respiratory and persistent infection of calves)													
Product Administration	One dose, subcutaneously													
Study Animals	Heifers (18 Vaccinates and 22 Controls), 13-16 months of age													
Challenge Description	Challenged with noncytopathic BVD2 PA131 strain, 12 months (374 days) after vaccination and at approximately 90 days of gestation													
Interval observed after challenge	Observed for 14 days after challenge. Blood collected on days 0, 2, 4, 6, 8, 10, 12 and 14 after challenge to evaluate viremia and leukopenia. Fetuses collected on day 65 after challenge.													
Results	<p>Results of the study are summarized as follows:</p> <p>Blood was evaluated for viremia (the presence of virus) and leukopenia (at least one white blood cell count no greater than 40% of pre-challenge baseline count).</p> <p>Positive for Viremia and Leukopenia:</p> <table border="1"> <thead> <tr> <th></th> <th>Viremia</th> <th>Leukopenia</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>1/18 (6%)</td> <td>1/18 (6%)</td> </tr> <tr> <td>Controls</td> <td>20/22 (91%)</td> <td>14/22 (50%)</td> </tr> </tbody> </table> <p>Calves (fetuses) were considered positive for persistent BVD infection if at least one fetal tissue was positive. The fetal tissues spleen, thymus, heart blood, and cerebellum were evaluated for the presence of BVD2 by virus isolation.</p> <p>Positive for BVD Persistent Infection:</p> <table border="1"> <tbody> <tr> <td>Vaccinates</td> <td>0/18 (0%)</td> </tr> <tr> <td>Controls</td> <td>21/22 (95%)</td> </tr> </tbody> </table> <p>See tables on the following pages for data.</p>		Viremia	Leukopenia	Vaccinates	1/18 (6%)	1/18 (6%)	Controls	20/22 (91%)	14/22 (50%)	Vaccinates	0/18 (0%)	Controls	21/22 (95%)
	Viremia	Leukopenia												
Vaccinates	1/18 (6%)	1/18 (6%)												
Controls	20/22 (91%)	14/22 (50%)												
Vaccinates	0/18 (0%)													
Controls	21/22 (95%)													
USDA Approval Date	October 4, 2011													

Viremia

Vaccinates (18 bovine)

Animal ID	Days Post-Challenge							
	0	2	4	6	8	10	12	14
9	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-
70	-	-	-	-	-	-	-	-
82	-	-	-	-	-	-	-	-
90	-	-	-	-	-	-	-	-
97	-	-	-	-	-	-	-	-
106	-	-	-	-	-	-	-	-
114	-	-	-	-	-	-	-	-
130	-	-	-	+	-	-	-	-
137	-	-	-	-	-	-	-	-
191	-	-	-	-	-	-	-	-
196	-	-	-	-	-	-	-	-
227	-	-	-	-	-	-	-	-
242	-	-	-	-	-	-	-	-
271	-	-	-	-	-	-	-	-
272	-	-	-	-	-	-	-	-

Controls (22 bovine)

Animal ID	Days Post-Challenge							
	0	2	4	6	8	10	12	14
2	-	-	-	-	+	-	-	-
3	-	-	-	+	+	+	-	-
7	-	-	-	+	+	-	-	-
12	-	-	-	-	-	-	-	-
20	-	-	-	-	+	+	-	-
24	-	-	-	+	+	-	-	-
27	-	-	-	-	-	-	-	-
81	-	-	-	+	+	-	-	-
88	-	-	-	+	+	+	+	-
91	-	-	-	+	-	-	-	-
145	-	-	-	+	+	+	-	-
157	-	-	-	-	+	-	-	-
159	-	-	+	+	+	+	-	+
168	-	-	-	+	+	-	-	-
170	-	-	-	+	+	-	-	-
199	-	-	-	+	+	-	-	-
202	-	-	-	+	+	-	-	-
211	-	-	-	-	+	+	-	-
224	-	-	+	+	+	+	-	-
248	-	-	-	+	+	-	-	-
269	-	-	-	+	+	+	-	-
279	-	-	-	+	+	-	-	-

+ = positive for virus (highlighted yellow)
 - = negative for virus

Leukopenia in Vaccinates (18 bovine)

Animal ID	White Blood Cell Count per each Day Post-Challenge									Overall Result
	Baseline (-2)	0	2	4	6	8	10	12	14	
9	4.9	4.3	6.5	8.8	6.8	7.4	8.6	8.5	6.4	-
21	7	6.6	9	5.4	7.2	7	5.4	5.9	6.7	-
43	4	5.2	9.8	9.1	3.7	7.9	6.5	6.3	7.5	-
57	5.4	6.6	6.8	5.2	5	6.6	8.3	6.2	7.6	-
70	4.6	8.6	6.2	6	4.5	6.4	6.1	9.6	5.4	-
82	6	6.7	8.4	10.2	5.5	9.9	6.8	7.3	6.9	-
90	5	6.5	5.9	9.6	4.9	6.3	6.6	6	7.1	-
97	5.2	6.7	6.8	7.7	6.4	5.5	6.8	7	4.6	-
106	3.8	8.1	6.3	6.5	4.7	8	7.2	5.8	6.6	-
114	6.4	6.9	6.1	5.1	6.3	6.9	6.9	5.3	5.3	-
130	5.4	4.5	7.2	5.5	3.6	9.4	6.4	5.2	6.6	-
137	8	5.1	4.9	6.5	10	7.4	9.1	6.4	4.7	+
191	3.6	7.6	7.9	7.2	4.3	7.2	5.7	6.5	5.5	-
196	4.2	8.2	4.3	6.5	8.4	8.3	5	4.9	4.8	-
227	3.7	4.8	5.8	4.8	5.3	8.2	6.2	9.2	6.5	-
242	8.7	10	9	7.1	5.6	8.8	7.4	5.4	5.5	-
271	5.4	6.1	5.6	5.9	5.8	10.9	6.7	7.1	10.1	-
272	5.9	5.3	4.2	5.8	4.7	5.1	5.9	5.7	7.1	-

White Blood Cell Count:

- Numerical values = white blood cell count in thousands of cells per cubic millimeter of blood (i.e. 4.9 equals 4,900 cells/mL³)

Overall Result:

- + = positive for leukopenia at least one day (highlighted yellow)
- = negative for leukopenia on every day

Leukopenia in Controls (22 bovine)

Animal ID	White Blood Cell Count per each Day Post-Challenge									Overall Result
	Baseline (-2)	0	2	4	6	8	10	12	14	
2	4.5	6.4	8.1	2.6	4.8	3.3	4.5	7.3	8.2	+
3	10.4	6	8.9	4.8	6.7	6.1	8.3	6.4	6.7	+
7	3.7	3.8	5.4	3.9	3.6	5.2	4.3	5.1	5.1	-
12	3.4	4.6	6.2	3.7	3.7	5.4	4.5	4.9	5.5	-
20	6.3	3.4	7.5	3.5	4.3	4.8	5.5	4.3	4.5	-
24	4.5	6	7	3.1	3.6	4.4	6.2	5.1	6.9	+
27	1.5	4.3	6	2.5	1.4	2.5	5	2.8	2.9	+
81	3.2	4	7.6	2.7	3.2	4	5.6	4.4	4.3	-
88	7.2	7.9	7.3	5.9	7.5	5.4	5	6.3	5.6	-
91	5.9	7.8	9.7	3.7	4.3	7.3	12.7	9.9	11	+
145	4.3	4.2	5.5	2.9	4.5	3.6	4.3	5.7	6.7	-
157	6.4	8.6	12.1	3.1	4.9	6.9	3.8	4.5	6.5	+
159	4.8	5.6	8.3	4.4	7	4.7	4	5.1	4.1	-
168	7.7	7	5.6	4	3.4	3.8	3.7	3.9	6.6	+
170	5.2	5.5	7	3	3.7	3.8	4	4.3	4.8	+
199	3.5	4.6	4.3	3.6	3.2	5.7	3.2	3.7	5.6	-
202	5.6	5.6	6	2	5.2	2.5	1.1	3.3	4.8	+
211	5.2	8.6	7.3	3.4	3.3	2.8	6.1	4.1	5.9	+
224	2.7	6.9	5	5	6.3	3	2.2	5.3	4.8	+
248	5.9	6.4	8.2	3.4	6.2	5.5	4.2	4.1	6.6	+
269	7.2	8.1	6.4	4.8	2.6	ND	4.2	3.9	4.7	+
279	5.7	7.4	6	3	4.2	3.1	4.7	3.3	3.2	+

White Blood Cell Count:

- Numerical values = white blood cell count in thousands of cells per cubic millimeter of blood (i.e. 4.9 equals 4,900 cells/mL³)

Overall Result:

- + = positive for leukopenia at least one day (highlighted yellow)
- = negative for leukopenia on every day

Persistent Infection of Calves

Vaccinates (18 bovine)

Animal ID	Result	Virus Isolation: BVD Type 2			
		Spleen	Thymus	Heart Blood	Brain
9	Negative	-	-	-	-
21	Negative	-	-	-	-
43	Negative	-	-	-	-
57	Negative	-	-	-	-
70	Negative	-	-	-	-
82	Negative	-	-	-	-
90	Negative	-	-	-	-
97	Negative	-	-	-	-
106	Negative	-	-	-	-
114	Negative	-	-	-	-
130	Negative	-	-	-	-
137	Negative	-	-	-	-
191	Negative	-	-	-	-
196	Negative	-	-	-	-
227	Negative	-	-	-	-
242	Negative	-	-	-	-
271	Negative	-	-	-	-
272	Negative	-	-	-	-

Controls (22 bovine)

Animal ID	Result	Virus Isolation: BVD Type 2			
		Spleen	Thymus	Heart Blood	Brain
2	Positive	+	-	+	+
3	Positive	+	+	+	+
7	Positive	+	+	+	+
12	Positive	+	+	+	+
20	Positive	+	+	+	+
24	Positive	+	+	+	+
27	Positive	+	+	+	+
81	Negative	-	-	-	-
88	Positive	+	+	+	+
91	Positive	+	+	+	+
145	Positive	+	+	+	+
157	Positive	-	+	+	+
159	Positive	+	+	+	+
168	Positive	+	+	+	+
170	Positive	+	+	+	+
199	Positive	+	+	+	+
202	Positive	+	+	+	+
211	Positive	+	+	+	+
224	Positive	+	+	+	+
248	Positive	+	+	+	+
269	Positive	+	+	+	+
279	Positive	+	+	+	+

Result:

Positive = positive for BVD persistent infection because at least one fetal tissue was positive, or heifer was open
 Negative = negative for BVD persistent infection because all fetal tissues were negative

Virus Isolation:

+ = fetal tissue positive for BVD2 by virus isolation
 - = fetal tissue negative for BVD2 by virus isolation

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	Demonstration of efficacy against IBR (respiratory disease)
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	May 4, 1994

Study Type	Efficacy									
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)									
Study Purpose	Demonstration of efficacy against IBR (reproductive disease) 12 months after vaccination									
Product Administration	One dose, subcutaneously approximately five months prior to breeding									
Study Animals	32 bovine (13 vaccinates and 19 controls), 7 - 9 months of age									
Challenge Description	Challenged with IBR Cooper strain 386 days after vaccination at approximately 7 months of gestation									
Interval observed after challenge	Cattle were observed daily after challenge and until calving for signs of abortion. Fetal tissues were evaluated for the presence of IBR and other causes of abortion.									
Results	<p>Cattle were considered affected if the fetus was aborted and testing results of the fetus were negative for other causes of abortion (Bovine viral diarrhea virus (BVDV) and abortifacient bacteria).</p> <p>Results of the study are summarized as follows:</p> <p>Abortions in vaccinates and controls:</p> <table border="1"> <thead> <tr> <th></th> <th>Non-Aborted</th> <th>Aborted</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>11/13 (84.6%)</td> <td>2/13 (15.4%)</td> </tr> <tr> <td>Controls</td> <td>1/19 (5.3%)</td> <td>18/19 (94.7%)</td> </tr> </tbody> </table> <p>See table on the following page for data.</p>		Non-Aborted	Aborted	Vaccinates	11/13 (84.6%)	2/13 (15.4%)	Controls	1/19 (5.3%)	18/19 (94.7%)
	Non-Aborted	Aborted								
Vaccinates	11/13 (84.6%)	2/13 (15.4%)								
Controls	1/19 (5.3%)	18/19 (94.7%)								
USDA Approval Date	October 5, 2011									

Abortion status and evaluation of fetal tissues:

Treatment	Animal	Abortion	IBR by PCR	IBR by Virus Isolation (VI)					BVDV by VI
				Brain	Kidney	Liver	Lung	Thymus	Same tissues
Vaccinates (13 bovine)	6	No	NA	NA	NA	NA	NA	NA	NA
	10	Yes	Negative	-	-	-	-	-	-
	34	No	NA	NA	NA	NA	NA	NA	NA
	45	No	NA	NA	NA	NA	NA	NA	NA
	89	No	NA	NA	NA	NA	NA	NA	NA
	117	No	NA	NA	NA	NA	NA	NA	NA
	155	No	NA	NA	NA	NA	NA	NA	NA
	176	Yes	Positive	-	-	-	-	+	-
	180	No	NA	NA	NA	NA	NA	NA	NA
	206	No	NA	NA	NA	NA	NA	NA	NA
	209	No	NA	NA	NA	NA	NA	NA	NA
Controls (19 bovine)	228	No	NA	NA	NA	NA	NA	NA	NA
	276	No	NA	NA	NA	NA	NA	NA	NA
	18	Yes	Positive	+	-	-	-	-	-
	26	Yes	Positive	-	-	-	-	-	-
	30	Yes	Positive	-	-	-	-	-	-
	41	Yes	Positive	-	-	-	-	-	-
	42	Yes	Positive	-	-	-	-	-	-
	47	Yes	Positive	-	-	-	-	-	-
	48	Yes	Positive	-	-	-	-	-	-
	62	Yes	Positive	-	-	-	+	-	-
	119	Yes	Positive	-	-	-	+	-	-
	128	No	NA	NA	NA	NA	NA	NA	NA
	154	Yes	Positive	-	-	-	-	-	-
	161	Yes	Positive	-	-	-	-	-	-
	174	Yes	Positive	-	-	-	-	-	-
187	Yes	Positive	-	-	-	+	-	-	
194	Yes	Positive	-	-	-	-	-	-	
210	Yes	Positive	-	-	-	-	-	-	
219	Yes	Positive	-	+	-	-	-	-	
257	Yes	Positive	+	-	-	-	-	-	
282	Yes	Positive	+	-	-	+	-	-	

NA = Not applicable since calf was not aborted.

Positive = Positive for the presence of IBR virus by PCR in all fetal tissues examined.

Negative = Negative for the presence of IBR virus by PCR in all fetal tissues (brain, kidney, liver, lung, and thymus).

+ = Positive for the presence of IBR or BVDV by virus isolation.

- = Negative for the presence of IBR or BVDV by virus isolation.

The same tissues were assessed for BVDV (brain, kidney, liver, lung, thymus).

Tissues were negative for abortifacient bacteria. Data not shown.

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
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	November 16, 2006

Study Type	Safety																								
Pertaining to	All fractions																								
Study Purpose	To demonstrate safety in pregnant heifers/cows and nursing calves																								
Product Administration	Two doses, administered subcutaneously. First vaccination given 1 – 2 months prior to breeding. Second vaccination given during a specified trimester of pregnancy.																								
Study Animals	<p><u>Site 1:</u> 2,063 cows and heifers received vaccine prior to breeding. 1,586 cows and heifers received vaccine or a placebo during pregnancy and are included in this summary.</p> <p><u>Site 2:</u> 120 calves from dams that received vaccine in the 2nd or 3rd trimester.</p>																								
Challenge Description	Not applicable																								
Interval observed after challenge	Not applicable																								
Results	<p>All cows and heifers were observed from pre-breeding vaccination through calving and calves were observed for 4 weeks postpartum. Results of the study are summarized as follows:</p> <p>Fetal Loss (Site 1):</p> <table border="1"> <thead> <tr> <th rowspan="2">Trimester</th> <th colspan="2">Vaccinates</th> <th colspan="2">Controls (Placebo)</th> </tr> <tr> <th>Enrolled</th> <th>Fetal Loss (%)</th> <th>Enrolled</th> <th>Fetal Loss (%)</th> </tr> </thead> <tbody> <tr> <td>1st</td> <td>306</td> <td>7 (2.3%)</td> <td>274</td> <td>6 (2.2%)</td> </tr> <tr> <td>2nd</td> <td>237</td> <td>1 (0.4%)</td> <td>235</td> <td>3 (1.3%)</td> </tr> <tr> <td>3rd</td> <td>267</td> <td>5 (1.9%)</td> <td>267</td> <td>6 (2.2%)</td> </tr> </tbody> </table> <p>The number of animals during pregnancy was reduced due to normal losses including dystocia, lameness, and non-study related causes (as affirmed by licensee). Fetal loss was due to abortion or open (non-pregnant). For all three trimesters, no cows or heifers (0.0%) in either group were diagnosed as having aborted due to Infectious Bovine Rhinotracheitis (IBR) or Bovine Virus Diarrhea Virus (BVDV). All tests for viral detection and isolation of IBR and BVDV on all fetal tissues were negative.</p> <p>Fetal Infection (Site 2): Serum samples were collected from calves prior to receiving colostrum. 61 calves were from cows vaccinated in the 2nd trimester and 59 calves were from cows vaccinated in the 3rd trimester. 6 serum samples were removed from the study due to equipment malfunction or concerns that colostrum was received. All valid samples tested negative for antibodies to IBR, BVD1 and BVD2. Serum samples were also negative for IBR by virus isolation and negative for BVD1 and BVD2 by PCR.</p>	Trimester	Vaccinates		Controls (Placebo)		Enrolled	Fetal Loss (%)	Enrolled	Fetal Loss (%)	1 st	306	7 (2.3%)	274	6 (2.2%)	2 nd	237	1 (0.4%)	235	3 (1.3%)	3 rd	267	5 (1.9%)	267	6 (2.2%)
Trimester	Vaccinates		Controls (Placebo)																						
	Enrolled	Fetal Loss (%)	Enrolled	Fetal Loss (%)																					
1 st	306	7 (2.3%)	274	6 (2.2%)																					
2 nd	237	1 (0.4%)	235	3 (1.3%)																					
3 rd	267	5 (1.9%)	267	6 (2.2%)																					

USDA Approval Date	January 11, 2008
---------------------------	------------------