Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	4461.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PYRAMID FP 10 - Boehringer Ingelheim (Canada) Ltd. PYRAMID FP 10 - No distributor specified Pyramid 10 - No distributor specified
Date of Compilation Summary	July 17, 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 clinical disease, leukopenia, and viremia
Product Administration	
Study Animals	Bovine
Challenge Description	BVD1b NY-1 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 14, 1994

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD)
Study Purpose	Demonstration of efficacy against persistent infection of calves with BVD Type 1
Product Administration	Pregnant heifers or cows prior to breeding
Study Animals	Bovine
Challenge Description	BVD1b 97B1415 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 10, 2003

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Virus Diarrhea (BVD)</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of efficacy against BVD Type 1 (respiratory disease) 217 days after vaccination</td></tr>
<tr><td>Product Administration</td><td>One dose, subcutaneously</td></tr>
<tr><td>Study Animals</td><td>46 bovine calves (23 vaccinates and 23 controls), 25 to 37 days of age</td></tr>
<tr><td>Challenge Description</td><td>Challenged with BVD Type 1b, Isolate CA0401186A, 217 days (7 months) after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Calves were observed and blood was collected for 14 days after challenge to evaluate viremia and leukopenia.</td></tr>
<tr><td>Results</td><td>Results of the study are summarized as follows:

Blood was evaluated for viremia (the presence of virus) and leukopenia (at least one white blood cell count below 60% of pre-challenge baseline).

Positive for Viremia and Leukopenia:
<table>
<tr><td></td><td>Viremia</td><td>Leukopenia</td></tr>
<tr><td>Vaccinates</td><td>0/23 (0%)</td><td>6/23 (26%)</td></tr>
<tr><td>Controls</td><td>22/23 (96%)</td><td>21/23 (91%)</td></tr>
</table>

See tables on the following pages for data.</td></tr>
<tr><td>USDA Approval Date</td><td>July 14, 2014</td></tr>
</table>

Viremia in Vaccinates (23 bovine)

Animal ID	Days Post-Challenge														Overall Result
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
21	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
61	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
64	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
67	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
68	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
73	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
82	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
86	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
87	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
94	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
97	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
102	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
104	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
108	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Viremia in Controls (23 bovine)

Animal ID	Days Post-Challenge														Overall Result
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
31	-	-	-	-	-	+	+	-	+	-	-	-	-	-	+
33	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+
36	-	+	+	+	-	+	-	-	-	-	-	-	-	-	+
38	-	-	-	+	+	+	+	-	+	-	-	-	-	-	+
44	-	-	-	+	+	+	-	-	-	-	-	-	-	-	+
47	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+
50	-	-	-	-	-	+	+	-	-	-	-	-	-	-	+
53	-	-	-	-	+	+	+	+	+	-	-	-	-	-	+
56	-	-	-	+	+	+	+	-	-	-	-	-	-	-	+
58	-	-	-	+	+	+	+	-	-	-	-	-	-	-	+
59	-	-	-	+	+	+	+	+	+	-	-	-	-	-	+
62	-	-	-	-	+	-	+	-	-	-	-	-	-	-	+
66	-	-	-	-	+	+	-	+	-	-	-	-	-	-	+
69	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+
70	-	-	-	-	+	+	+	-	-	-	-	-	-	-	+
74	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
85	-	-	-	-	+	+	-	-	-	-	-	-	-	-	+
89	-	-	-	-	+	+	+	-	-	-	-	-	-	-	+
92	-	-	-	-	-	+	+	-	-	-	-	-	-	-	+
98	-	-	-	-	+	+	+	-	-	-	-	-	-	-	+
101	-	-	-	-	-	+	+	+	-	-	-	-	-	-	+
106	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+
107	-	-	-	-	+	+	+	-	-	-	-	-	-	-	+

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

Leukopenia in Vaccinates (23 bovine)

ID	White Blood Cell Count per each Day Post-Challenge															Overall Result
	Base -line	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
21	13.5	10.4	11.3	11.6	11.9	11.3	12.4	12.2	11.6	12.4	9.6	9.6	9.3	9.7	10.4	-
32	8.4	8.1	7.8	7.9	NA	9.9	8.9	9.7	8.9	7.1	6.6	8	8.4	10.7	12	-
34	8.9	8.7	9	9.3	9.5	8.5	8.9	9	8.6	8	8.2	4.7	5.1	6.9	8.6	+
37	13.9	12.4	12.7	12.6	11.9	11.6	11	11.4	9.4	9.3	9	9.9	10.1	10.1	9.9	-
41	8.1	8.3	7.8	9.1	8.3	7.5	7.3	7.4	7.5	5.4	5.3	5.1	6.2	7.8	8.1	-
43	8.0	7.7	8	8.8	8.1	8.6	8	8.9	7.8	8.2	6	6.9	8.1	7.4	6.8	-
48	6.2	6.6	6.8	7	6.7	6.5	6.5	6.8	7.2	3.1	3.8	5	5.6	5.8	6.1	+
49	11.1	10.6	10.9	11.1	11.8	10.5	9.4	10.1	10.4	10.5	8	8.8	8.6	10.9	11.9	-
51	8.0	8.5	9.4	10.8	10.4	11.3	9.7	10.1	10.3	8.7	5.5	6.7	7.4	7.5	8.2	-
57	8.5	9.4	9.6	9.1	9.7	8.8	9.4	9.1	9	8.8	8.4	7	8	7.5	7.3	-
61	7	7	6.8	7.9	4.6	3.9	4.5	6.6	7	6.8	6.3	8.2	8.8	8	7.9	+
64	8.1	6.6	6.1	6.6	7.2	6.2	6.9	7.2	7.1	7.4	7.1	6.8	7.8	9.5	9	-
67	6.2	5.8	5.9	6.6	6.7	6.3	3.5	4.7	5	5.1	5.4	6.4	6.4	8.2	6.1	+
68	7.6	8.2	8.5	8.7	8.7	7	5.1	5.6	6.3	6.6	7.2	7.9	8.1	9.3	9.4	-
73	8.0	8	7.9	8	8.1	7.8	7.7	6.1	5.7	5.8	5.9	6.1	7.3	7.4	9.2	-
82	11.6	11.1	11.2	17.2	12.1	11.6	11.6	11	11.5	11.4	5.7	8.1	9.6	11.5	10.8	+
86	6.6	7.2	7.1	6.8	6.8	5.9	6.3	6.1	5.8	6.7	4.2	4.6	5.9	5.9	7.2	-
87	9.2	9.4	9.9	10	7.4	8.3	7.5	10.4	8.8	8.6	9.7	9.1	8.9	9.1	9.6	-
94	11.6	11.2	11.4	10.6	10.1	9.3	9.3	9.4	9.9	10.2	8.3	8.6	9.4	11.4	11.8	-
97	6.4	6.8	7	8.1	8.3	7.7	7.4	7.9	8.3	7.5	4.8	5.3	5.7	6.6	5.8	-
102	8.7	8.3	8.8	8.7	8.9	8.2	8.2	8.5	8	6	3.8	5.5	6.3	7.1	8.1	+
104	8.3	8.4	8.6	9.2	8.9	7.9	8.1	8.9	8.5	6.9	5.3	6.7	6.7	9.9	7.9	-
108	8.1	8.1	9	7.7	8.4	11.4	7.8	9.3	11.9	10.3	10.3	8	12.7	10.6	10.2	-

White Blood Cell Count:

- Baseline is the average white blood cell (WBC) counts from 3 consecutive days, prior to challenge
- Numerical values = white blood cell count in K/µL
- Highlighted yellow = positive for leukopenia, meaning a 40% or more reduction in the total WBC count compared to baseline on that day
- NA = not applicable / no measurement on that day

Overall Result:

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

Leukopenia in Controls (23 bovine)

ID	White Blood Cell Count per each Day Post-Challenge															Overall Result
	Base -line	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
31	7.8	7.7	7.3	3.8	NA	4.5	3.7	3.9	6.1	10.6	7	5.9	5.5	5.9	3.2	+
33	11.3	10.5	11.9	6.5	7	7.3	5.7	6	10.3	7.9	6.8	7	7.4	8.1	7.7	+
36	8.9	9.2	8.8	5.1	6.4	5.7	5.3	5.2	6.6	7.5	6.3	5.7	5.9	5.9	6	+
38	6.5	5.9	7	4.6	4.6	3.9	3.6	3.4	7	7.3	6.1	5.4	5.3	5.6	5	+
44	10.3	10.2	10	4.1	6.2	5.8	4.3	7.3	12.7	8	5.4	5.7	6.3	5.5	5.5	+
47	7.9	8.1	7.6	4.8	5.9	5.8	4.5	5.3	7.9	6.5	6.2	5.8	5.6	5.6	6	+
50	8.2	8.9	8.9	5.9	4.6	6	5.1	6.3	10.4	8.9	6.3	5.1	5.1	5.7	5.6	+
53	7.5	8.3	8.5	3.9	4.5	4.3	3.1	3.4	3.6	7.5	6.1	4.4	5.6	5.8	5.5	+
56	9.8	7.6	9.1	3.9	6	4.5	4.4	5.3	12.2	9.8	5.4	5.2	6	5.5	6.3	+
58	8.3	8.7	9.8	5.7	6.3	7.1	5.1	5.2	8.2	8.4	6.1	6.4	7.4	6.2	6.5	-
59	10.1	11.1	12.2	8.5	7.3	8.7	7.6	7.8	9.4	12.7	13	9.9	9.5	9.9	21.6	-
62	9.5	10.2	9.8	4.9	5.5	5.1	4.2	3.9	7.5	10.7	8.6	7	6.1	6.2	5.5	+
66	6.7	8.5	8	4.5	6	5.2	4.5	5.8	7	5.8	4.8	4.6	5.1	5.4	3.9	+
69	11.1	12.1	11.4	5.1	8.1	8.8	7.2	9.4	11.3	10.5	7.8	7.4	7.1	7.4	7.7	+
70	10.7	10.1	9	4.4	6	5.8	4.4	4.5	7.5	10.8	8.5	7.4	5.6	6.4	5.8	+
74	5.8	6.2	6.4	4.2	4.7	4.2	3.3	3	4	7	5.2	4.4	4.6	4.1	4.5	+
85	8.6	8	7.8	5.7	6.8	5.4	4.5	4.3	5	6.1	6.3	7.4	7.2	7.6	7.4	+
89	8.9	8.4	8.5	3.9	5.8	6.1	4.6	4.1	9.1	8.6	5.7	4.7	5.2	5.1	5.7	+
92	7.8	7.4	5.9	4.4	4.6	3.8	3.2	3.6	4.1	4.6	3.6	3.8	3.8	4.5	4.4	+
98	7.9	7.4	8	4.5	5.9	4.2	4.1	4.1	6.5	7.3	6.5	5.8	6.1	5.9	5.8	+
101	9.9	9.3	10.5	8.5	7.6	7.2	5.6	5.5	5.3	13.4	9.6	7.2	6.5	7	5.4	+
106	7.1	7.2	7.3	4.4	5.3	4.6	3.7	5.2	7.6	5.3	5.1	6.4	5.6	6.3	6.9	+
107	10.7	10.5	10.1	6.7	7.9	7	5.5	5.7	7.8	8.9	8.7	7.5	7.1	7.6	8.8	+

White Blood Cell Count:

- Baseline is the average white blood cell (WBC) counts from 3 consecutive days, prior to challenge
- Numerical values = white blood cell count in K/µL
- Highlighted yellow = positive for leukopenia, meaning a 40% or more reduction in the total WBC count compared to baseline on that day
- NA = not applicable / no measurement on that day

Overall Result:

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

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD)
Study Purpose	Demonstration of efficacy against persistent infection of calves with BVD Type 2
Product Administration	Pregnant heifers or cows prior to breeding
Study Animals	Bovine
Challenge Description	BVD2a 96B2222 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 10, 2003

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD)
Study Purpose	Demonstration of efficacy against BVD Type 2 clinical disease, leukopenia, and viremia
Product Administration	
Study Animals	Bovine
Challenge Description	BVD2a IAF 103, BT-4A-2 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 22, 2004

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	December 2, 2002

Study Type	Efficacy
Pertaining to	*Leptospira canicola*
Study Purpose	Demonstration of efficacy against *Leptospira canicola*
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	December 3, 1997

Study Type	Efficacy
Pertaining to	*Leptospira grippotyphosa*
Study Purpose	Demonstration of efficacy against *Leptospira grippotyphosa*
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	December 3, 1997

Study Type	Efficacy
Pertaining to	*Leptospira hardjo*
Study Purpose	Demonstration of efficacy against *Leptospira hardjo*
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. Study data, however, are no longer available.
USDA Approval Date	October 1, 1998

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Leptospira hardjo</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of efficacy against Leptospira borgpetersenii serovar hardjo-bovis</td></tr>
<tr><td>Product Administration</td><td>Two doses, 21 days apart, Subcutaneously</td></tr>
<tr><td>Study Animals</td><td>29 bovine (16 vaccinates, 13 controls), 6-10 month old heifers</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Leptospira borgpetersenii serovar hardjo-bovis on 62, 63 and 64 days after the second vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Cattle were observed daily for 10 days after challenge, then three times weekly for 7 weeks. Urine samples were taken weekly for 8 weeks. On day 62 - 63 after challenge, kidneys were cultured for Leptospira isolation.</td></tr>
<tr><td>Results</td><td>Results of the study are summarized as follows:

Urine cultures were positive for Leptospira on at least one day:
<table>
<tr><th>Group</th><th># Positive / Total</th><th>% Affected</th><th>% Unaffected</th></tr>
<tr><td>Vaccinates</td><td>1 / 16</td><td>6%</td><td>94%</td></tr>
<tr><td>Controls</td><td>13 / 13</td><td>100%</td><td>0%</td></tr>
</table>
Kidney cultures were positive for Leptospira at necropsy:
<table>
<tr><th>Group</th><th># Positive / Total</th><th>% Affected</th><th>% Unaffected</th></tr>
<tr><td>Vaccinates</td><td>0 / 16</td><td>0%</td><td>100%</td></tr>
<tr><td>Controls</td><td>13 / 13</td><td>100%</td><td>0%</td></tr>
</table>
See tables on the following pages for data.</td></tr>
<tr><td>USDA Approval Date</td><td>January 14, 2015</td></tr>
</table>

Urine and Kidney Cultures:

Vaccinates:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Overall Kidney Outcome
	1	2	3	4	5	6	7	8		
7	-	-	-	-	-	-	-	-	Negative	Negative
12	-	-	-	-	-	-	-	-	Negative	Negative
17	-	-	-	-	-	-	-	-	Negative	Negative
22	-	-	-	-	-	-	-	-	Negative	Negative
29	-	-	-	-	-	-	-	-	Negative	Negative
36	-	-	-	-	-	-	-	-	Negative	Negative
37	-	-	-	-	-	-	-	-	Negative	Negative
39	-	-	-	-	-	-	-	-	Negative	Negative
45	-	-	-	-	-	-	-	-	Negative	Negative
47	-	-	+	-	-	-	-	-	Positive	Negative
53	-	-	-	-	-	-	-	-	Negative	Negative
55	-	-	-	-	-	-	-	-	Negative	Negative
56	-	-	-	-	-	-	-	-	Negative	Negative
62	-	-	-	-	-	-	-	-	Negative	Negative
63	-	-	-	-	-	-	-	-	Negative	Negative
64	-	-	-	-	-	-	-	-	Negative	Negative

Controls:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Overall Kidney Outcome
	1	2	3	4	5	6	7	8		
6	-	+	+	+	+	+	+	+	Positive	Positive
10	-	+	+	+	+	+	+	+	Positive	Positive
18	-	+	+	+	+	+	+	+	Positive	Positive
28	-	+	+	+	+	+	+	+	Positive	Positive
32	-	-	+	+	+	+	+	+	Positive	Positive
41	-	-	+	+	+	+	+	+	Positive	Positive
43	-	+	+	+	+	+	+	+	Positive	Positive
49	-	+	+	+	+	+	+	+	Positive	Positive
50	-	-	+	+	+	+	-	+	Positive	Positive
59	-	+	+	+	+	+	+	+	Positive	Positive
60	-	+	+	+	+	+	+	+	Positive	Positive
67	-	-	+	+	+	+	+	+	Positive	Positive
68	-	+	+	+	+	+	+	+	Positive	Positive

Weekly Urine Observations:
- = Urine sample was negative for *Leptospira*
+ = Urine sample was positive for *Leptospira* (highlighted yellow)

Overall Urine / Kidney Outcome:
Negative = All urine / kidney samples were negative for *Leptospira*
Positive = At least one urine / kidney sample was positive for *Leptospira* (highlighted yellow)

Study Type	Efficacy
Pertaining to	*Leptospira icterohaemorrhagiae*
Study Purpose	Demonstration of efficacy against *Leptospira icterohaemorrhagiae*
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	December 3, 1997

Study Type	Efficacy
Pertaining to	*Leptospira pomona*
Study Purpose	Demonstration of efficacy against *Leptospira pomona*
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	December 3, 1997

Study Type	Efficacy
Pertaining to	Bovine Parainfluenza Type 3 (PI_3)
Study Purpose	Demonstration of efficacy against PI_3
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	June 10, 2002

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	Demonstration of efficacy against BRSV
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	January 5, 2006

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	December 10, 2002

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine: pregnant cows and calves nursing pregnant cows provided the cows were vaccinated pre-breeding
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	December 6, 2005