Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
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)	Bovilis Vista 5 L5 SQ - Abdulrehman Algosabi GTC (Saudi Arabia) - Merck Sharpe and Dohme (MSD) Bovilis Vista 5 L5 SQ - MSD Salud Animal Columbia S.A.S. Bovilis Vista 5 L5 SQ - MSD Salud Animal Columbia S.A.S. - Merck Sharpe and Dohme (MSD) Bovilis Vista 5 L5 SQ - Merck Animal Health Bovilis Vista 5 L5 SQ - Merck Sharpe and Dohme (MSD) Bovilis Vista 5 L5 SQ - No distributor specified Bovilis Vista L5 SQ - MSD Animal Health Bovilis Vista L5 SQ - MSD Salud Animal Columbia S.A.S. - Merck Sharpe and Dohme (MSD) Bovilis Vista L5 SQ - No distributor specified Vista 5 L5 SQ - Merck Animal Health Vista 5 L5 SQ - No distributor specified
Date of Compilation Summary	December 15, 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 Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV1.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b NY-1 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 20, 2004

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

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV1 206 days after vaccination.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b strain SD02 BVD09
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	October 6, 2005

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV1 206 days after vaccination.
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	October 6, 2005

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV2.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV2a strain 1373
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 10, 2003

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV2)
Study Purpose	To demonstrate efficacy against persistent infection of calves caused by BVDV2
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 2 strain SD02 BVD05
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	April 25, 2005

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

Viremia of Challenged Heifers

(Vaccinate Group)

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

0=negative; 1=positive.

(Control Group)

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

0=negative; 1=positive.

Virus Isolation from Fetal Samples

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

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

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV2 200 days after vaccination.
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 22, 2006

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against disease caused by IBR
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 29, 2004

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against abortions caused by IBR
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 27, 2005

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate efficacy against abortions caused by IBR at 217 days post vaccination.
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 16, 2006

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate efficacy against respiratory disease caused by IBR 182 days after vaccination.
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	March 30, 2004

Study Type	Efficacy
Pertaining to	*Leptospira canicola*
Study Purpose	To demonstrate effectiveness against disease caused by *L. canicola*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 10, 2005

Study Type	Efficacy
Pertaining to	*Leptospira grippotyphosa*
Study Purpose	To demonstrate effectiveness against disease caused by *L. grippotyphosa*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 10, 2005

Study Type	Efficacy
Pertaining to	*Leptospira hardjo*
Study Purpose	To demonstrate effectiveness against disease caused by *L. hardjo*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 24, 2004

<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>To demonstrate effectiveness against urinary shedding of L. hardjo</td></tr>
<tr><td>Product Administration</td><td>1 dose administered by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>29 calves, > 6 months of age, 14 vaccinates and 15 controls</td></tr>
<tr><td>Challenge Description</td><td>All calves were challenged with L. hardjo 21 days after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All calves were monitored daily for 30 days for clinical signs of disease. Urine samples were taken on days 16 (Week 2), 23 (Week 3) and 30 (Week 4) post challenge for Leptospira isolation.</td></tr>
<tr><td>Results</td><td><u>Leptospira Isolation:</u> A calf was considered positive if leptospires were isolated from the urine during any of the four post-challenge weeks.
<table>
<tr><th>Group</th><th># of Animals</th><th># Positive</th><th>Percent (%)</th></tr>
<tr><td>Vaccinates</td><td>14</td><td>0</td><td>0</td></tr>
<tr><td>Controls</td><td>15</td><td>15</td><td>100</td></tr>
</table>
Raw data shown on the attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>March 27, 2012</td></tr>
</table>

L. hardjo Urine Isolations

Group	Animal No.	Post-challenge Week		
		2	3	4
Control	507	+	-	-
	509	+	+	-
	510	+	+	+
	517	+	+	+
	518	+	+	-
	519	+	-	-
	520	-	+	-
	521	-	+	-
	523	+	-	-
	526	+	-	-
	527	+	+	-
	529	+	-	-
	531	-	+	-
	533	+	+	-
	540	+	+	-
Vaccinated	508	-	-	-
	511	-	-	-
	512	-	-	-
	514	-	-	-
	516	-	-	-
	522	-	-	-
	524	-	-	-
	525	-	-	-
	532	-	-	-
	536	-	-	-
	537	-	-	-
	541	-	-	-
	542	-	-	-
	543	-	-	-

Study Type	Efficacy
Pertaining to	*Leptospira icterohaemorrhagiae*
Study Purpose	To demonstrate effectiveness against disease caused by *L. icterohaemorrhagiae*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 22, 2004

Study Type	Efficacy
Pertaining to	*Leptospira pomona*
Study Purpose	To demonstrate effectiveness against disease caused by *L. pomona*
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 24, 2004

Study Type	Efficacy
Pertaining to	Parainfluenza$_3$ Virus (PI3)
Study Purpose	To demonstrate effectiveness against shedding caused by PI3
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	April 12, 2005

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	To demonstrate effectiveness against BRSV
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 3, 2004

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>NA</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety in pregnant cows or in calves nursing pregnant cows if previously vaccinated pre-breeding with same product</td></tr>
<tr><td>Product Administration</td><td>One dose of test product was administered subcutaneously 30-60 days before breeding to all study animals. Then the test or control product was given during the targeted trimester of gestation.
<u>Test product:</u> Contains modified live virus fractions
<u>Control product:</u> Product of similar composition except virus fraction(s) are killed</td></tr>
<tr><td>Study Animals</td><td>Pregnant cows: separate groups vaccinated at each trimester of gestation. Similar sized groups in each trimester were maintained as controls.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>No challenge. After vaccination, observed daily through birth of calves. Calves monitored for 48 hours (bull calves) or 4 weeks (heifer calves).</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th></th><th></th><th colspan="4">Number Pregnant Cows</th></tr>
<tr><th>Trimester</th><th>Vaccinated During Gestation With</th><th>Vaccinated</th><th>Removed from study[a]</th><th>Unrelated Abortions[b]</th><th>Abortions[c]</th></tr>
<tr><td>1</td><td>Control Product</td><td>233</td><td>7</td><td>2</td><td>2</td></tr>
<tr><td>1</td><td>Test Product</td><td>235</td><td>4</td><td>3</td><td>1</td></tr>
<tr><td>2</td><td>Control Product</td><td>230</td><td>0</td><td>2</td><td>1</td></tr>
<tr><td>2</td><td>Test Product</td><td>231</td><td>2</td><td>6</td><td>1</td></tr>
<tr><td>3</td><td>Control Product</td><td>224</td><td>2</td><td>5</td><td>1</td></tr>
<tr><td>3</td><td>Test Product</td><td>216</td><td>1</td><td>8</td><td>0</td></tr>
</table>
[a]Removals affirmed by study cooperator to be unrelated to vaccination.
[b]Abortions affirmed by study cooperator to have known cause, unrelated to infectious bovine rhinotracheitis or bovine virus diarrhea viruses
[c]Abortions with unknown causes OR related to infectious bovine rhinotracheitis or bovine virus diarrhea viruses

<table>
<tr><th></th><th></th><th colspan="2">Number of Calves</th></tr>
<tr><th>Trimester</th><th>Vaccinated During Gestation With</th><th>Live Births[a]</th><th>Mortality Prior to End of Observation Period</th></tr>
<tr><td>1</td><td>Control Product</td><td>224</td><td>4</td></tr>
<tr><td>1</td><td>Test Product</td><td>229</td><td>6</td></tr>
<tr><td>2</td><td>Control Product</td><td>233</td><td>5</td></tr>
<tr><td>2</td><td>Test Product</td><td>230</td><td>2</td></tr>
<tr><td>3</td><td>Control Product</td><td>223</td><td>14</td></tr>
<tr><td>3</td><td>Test Product</td><td>221</td><td>5</td></tr>
</table>
[a]Live births include twins
</td></tr>
<tr><td>USDA Approval Date</td><td>May 9, 2013</td></tr>
</table>

Study Type	Safety
Pertaining to	ALL
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	June 16, 2004

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

Summary of the results as follows:

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

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