Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2665.02
True Name	Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	L5 SQ - MSD Salud Animal Columbia S.A.S. L5 SQ - Merck Animal Health L5 SQ - Merck Sharpe and Dohme (MSD)
Date of Compilation Summary	September 18, 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	*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	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