



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	26M1.00
True Name	Leptospira Hardjo-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	November 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira hardjo</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Leptospira hardjo</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	October 1, 1998

<b>Study Type</b>	Efficacy																								
<b>Pertaining to</b>	<i>Leptospira hardjo</i>																								
<b>Study Purpose</b>	Demonstration of efficacy against <i>Leptospira borgpetersenii</i> serovar <i>hardjo-bovis</i>																								
<b>Product Administration</b>	Two doses, 21 days apart, Subcutaneously																								
<b>Study Animals</b>	29 bovine (16 vaccinates, 13 controls), 6-10 month old heifers																								
<b>Challenge Description</b>	Challenged with <i>Leptospira borgpetersenii</i> serovar <i>hardjo-bovis</i> on 62, 63 and 64 days after the second vaccination																								
<b>Interval observed after challenge</b>	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 <i>Leptospira</i> isolation.																								
<b>Results</b>	<p>Results of the study are summarized as follows:</p> <p>Urine cultures were positive for <i>Leptospira</i> on at least one day:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive / Total</th> <th>% Affected</th> <th>% Unaffected</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Kidney cultures were positive for <i>Leptospira</i> at necropsy:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive / Total</th> <th>% Affected</th> <th>% Unaffected</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>See tables on the following pages for data.</p>	Group	# Positive / Total	% Affected	% Unaffected	Vaccinates	1 / 16	6%	94%	Controls	13 / 13	100%	0%	Group	# Positive / Total	% Affected	% Unaffected	Vaccinates	0 / 16	0%	100%	Controls	13 / 13	100%	0%
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<b>USDA Approval Date</b>	January 14, 2015																								

## 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)

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira pomona</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Leptospira pomona</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	December 3, 1997

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	December 10, 2002