Summary of Studies Supporting USDA Product Licensure

Establishment Name	American Animal Health, Inc.
USDA Vet Biologics Establishment Number	315
Product Code	7935.04
True Name	Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	MH-PM - No distributor specified Pulmo-Guard PH-M - Agri Laboratories, Ltd. Pulmo-Guard PH-M - Huvepharma, Inc
Date of Compilation Summary	November 08, 2021

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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease</td></tr>
<tr><td>Product Administration</td><td>Two doses, given subcutaneously, three weeks apart</td></tr>
<tr><td>Study Animals</td><td>Calves, 2.5 month of age, 20 vaccinates and 10 controls</td></tr>
<tr><td>Challenge Description</td><td>M. haemolytica, 2 weeks after second vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 4 days for clinical signs and mortality at which time lung samples were evaluated</td></tr>
<tr><td>Results</td><td>Clinical signs were not observed in any animals.

Summary of mortality after challenge
<table>
<tr><th>Cohort</th><th>Treatment</th><th>No. dead*</th><th>No. survived</th><th>Total</th><th>Mortality</th></tr>
<tr><td rowspan="2">#1</td><td>Vaccinate</td><td>3</td><td>7</td><td>10</td><td>30%</td></tr>
<tr><td>Placebo</td><td>5</td><td>0</td><td>5</td><td>100%</td></tr>
<tr><td rowspan="2">#2</td><td>Vaccinate</td><td>4</td><td>6</td><td>10</td><td>40%</td></tr>
<tr><td>Placebo</td><td>5</td><td>0</td><td>5</td><td>100%</td></tr>
</table>
*Placebo and vaccinate animals had M. haemolytica isolated from lung samples

Raw data is in the following table.</td></tr>
<tr><td>USDA Approval Date</td><td>January 9, 2012</td></tr>
</table>

Cohort	Treatment	Animal ID	DPC1	DPC2	DPC3	DPC4
#1	Vaccinate	B46		×		
		G54				
		G59		×		
		P10				
		P27				
		P35				
		P42				
		P45				
		Y61		×		
		Y63				
	Placebo	G55				×
		P18	×			
		P26	×			
		P28	×			
		P39	×			
#2	Vaccinate	352				
		354				
		355	×			
		358	×			
		361				
		362	×			
		363				
		364				
		368				
		369	×			
	Placebo	351	×			
		357	×			
		359	×			
		367	×			
		371	×			

DPC = Day Post Challenge, × = Mortality and *M. haemolytica* isolated from lung samples.

Study Type	Efficacy
Pertaining to	*Pasteurella multocida*
Study Purpose	Demonstration of efficacy against *Pasteurella multocida*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>Two doses, given subcutaneously, three weeks apart</td></tr>
<tr><td>Study Animals</td><td>456 calves total at 4 sites. Minimum age 30 days.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for 2-3 hours (Study Day 0) and again at 18-24 hours after each injection and then daily for 14 days. Palpation of injection sites was performed 4-6 days and 21 days after each injection.</td></tr>
<tr><td>Results</td><td>Only injection site reactions were observed as follows:
<table>
<tr><td rowspan="2">Study Days</td><td colspan="4">Injection Site Swellings</td><td rowspan="2">Total Number Animals</td></tr>
<tr><td>0 cm</td><td><1.5 cm</td><td>1.5-5 cm</td><td>>5 cm</td></tr>
<tr><td>SD 4-6</td><td>254</td><td>56</td><td>139</td><td>7</td><td>456</td></tr>
<tr><td>SD 21</td><td>365</td><td>65</td><td>25</td><td>1</td><td>456</td></tr>
<tr><td>SD 25-27</td><td>212</td><td>46</td><td>193</td><td>5</td><td>456</td></tr>
<tr><td>SD 42</td><td>382</td><td>52</td><td>22</td><td>0</td><td>456</td></tr>
</table></td></tr>
<tr><td>USDA Approval Date</td><td>November 9, 2012</td></tr>
</table>