Summary of Studies Supporting USDA Product Licensure

Establishment Name	ProtaTek International, Inc.
USDA Vet Biologics Establishment Number	329
Product Code	2775.06
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s)/Distributor (if different from manufacturer)	MycoGard-1 - PharmGate Animal Health
Date of Compilation Summary	February 08, 2017

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>Mycoplasma hyopneumoniae</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease</td></tr>
<tr><td>Product Administration</td><td>One dose, given intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>Commercial pigs, 12 days ±1 day of age. 22 vaccinates and 21 controls.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 33 days after vaccination with Mycoplasma hyopneumoniae.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs evaluated 37 days after challenge for percent of the lung mass that was abnormal (consolidated).</td></tr>
<tr><td>Results</td><td>Summary of lung consolidation
<table>
<tr><th>Treatment Group</th><th colspan="2">Lung consolidation</th></tr>
<tr><td></td><td>0%</td><td>≥ 0.50%</td></tr>
<tr><td>Vaccinates</td><td>11/22</td><td>9/22</td></tr>
<tr><td>Controls</td><td>2/20</td><td>18/20</td></tr>
</table>
1 pig in the control group died, unrelated to the study, prior to challenge.

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>12/17/2013</td></tr>
</table>

Lung consolidation scores (%), in order of rank:

Vaccinate	Control
0	0
0	0
0	0.50
0	1.00
0	1.00
0	4.00
0	5.00
0	5.50
0	6.00
0	6.25
0	6.50
0.50	6.75
0.50	8.00
1.00	9.00
1.00	9.75
1.25	10.00
1.50	11.75
2.50	12.50
3.00	14.25
5.00	16.50
6.25	
15.50	

<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>1 dose administered by intramuscular route</td></tr>
<tr><td>Study Animals</td><td>832 pigs ranging in age from 10 days to 3 weeks at each of 3 sites. All were vaccinated intramuscularly (IM). 1/3 of the pigs at each site were of minimum age recommended for product administration.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed immediately following injection and then daily through 21 days after vaccination.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (832 Total Pigs)</th><th>IM Injection</th></tr>
<tr><td>Injection Site Swelling* (transient, ≤2 cm diameter)</td><td>2</td></tr>
<tr><td>Respiratory Distress</td><td>0</td></tr>
<tr><td>Pain on injection</td><td>0</td></tr>
<tr><td>Pig Deaths (Affirmed by licensee to have cause other than vaccination)</td><td>9</td></tr>
<tr><td>No adverse events</td><td>821</td></tr>
</table>
*Injection site swelling resolved by Day 7 post-vaccination
</td></tr>
<tr><td>USDA Approval Date</td><td>06/21/2016</td></tr>
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