Summary of Studies Supporting USDA Product Licensure

Establishment Name	Pharmgate Biologics, Inc.
USDA Vet Biologics Establishment Number	329
Product Code	19S1.R0
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PRRSGard - Pharmgate Biologics Inc.
Date of Compilation Summary	April 19, 2019

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>Porcine Respiratory and Reproductive Syndrome (PRRS)</td></tr>
<tr><td>Study Purpose</td><td>Pivotal efficacy against PRRS-associated disease</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>Commerical pigs, 21 days ±1 day of age and randomly divided into 25 vaccinates and 25 controls.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 49 days after vaccination with virulent PRRS virus</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs evaluated 14 days after challenge for percent of the lung mass that was abnormal (consolidated).</td></tr>
<tr><td>Results</td><td>Lung lesion score (LLS) reflects the approximate volume percentage of the lung that is affected by PRRS-associated pneumonia, and is expressed as %.

5-number summary of the LLS between vaccinates and controls
<table>
<tr><td></td><td>Minimum</td><td>Q1</td><td>Median</td><td>Q3</td><td>Maximum</td></tr>
<tr><td>Vaccinates</td><td>0.00</td><td>0.30</td><td>0.95</td><td>4.70</td><td>36.00</td></tr>
<tr><td>Controls</td><td>0.20</td><td>3.50</td><td>8.25</td><td>30.75</td><td>63.50</td></tr>
</table>

Raw data shown on attached pages.</td></tr>
<tr><td>USDA Approval Date</td><td>04/17/2013</td></tr>
</table>

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

Vaccinate	Control
0	0.20
0	1.1
0	1.50
0.10	1.95
0.20	2.00
0.25	2.95
0.30	3.50
0.40	4.40
0.50	4.50
0.50	5.50
0.55	5.85
0.70	7.45
0.95	8.25
1.20	13.00
1.25	15.50
1.45	16.00
1.85	16.20
3.15	22.0
4.7	30.75
5.45	31.00
9.95	32.20
18.75	36.00
27.5	38.00
29.0	49.50
36.0	63.50

<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>622 pigs ranging in age from 21-24 days 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 (622 Total Pigs)</th><th>IM Injection</th></tr>
<tr><td>Injection Site Swelling* (transient, ≤3 cm diameter)</td><td>3</td></tr>
<tr><td>Respiratory Distress</td><td>15</td></tr>
<tr><td>Pain on injection</td><td>0</td></tr>
<tr><td>Emesis</td><td>10</td></tr>
<tr><td>Cyanosis</td><td>7</td></tr>
<tr><td>Seborrhea</td><td>1</td></tr>
<tr><td>Claw/hoof/nail disorder, nonspecific</td><td>1</td></tr>
<tr><td>Ataxia</td><td>5</td></tr>
<tr><td>Pig Deaths (Can not rule out vaccination as cause)</td><td>3</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>604</td></tr>
</table>
*Injection site swelling resolved by Day 8 post-vaccination
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<tr><td>USDA Approval Date</td><td>February 20, 2019</td></tr>
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