Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19S1.22
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prime Pac PRRS RS - Merck Animal Health Prime Pac PRRS RS - No distributor specified
Date of Compilation Summary	December 18, 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>Porcine Reproductive and Respiratory Syndrome Virus</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>single dose</td></tr>
<tr><td>Study Animals</td><td>16 litters of 8 pigs each, divided into 4 vaccinates and 4 controls (128 total pigs), 22-23 days of age, negative for anti-PRRSv antibodies and PCV2 viremia at 2 independent study sites.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged with PRRSv, 4.5 weeks after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 14 days post-challenge.</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 %.

<table>
<tr><td colspan="6">5-number summary of the LLS across all litters</td></tr>
<tr><td></td><td>Minimum</td><td>Q 1</td><td>Median</td><td>Q 3</td><td>Maximum</td></tr>
<tr><td>Site 1--Vaccinate</td><td>0</td><td>4</td><td>8</td><td>15</td><td>37</td></tr>
<tr><td>Site 1-Placebo</td><td>6</td><td>20</td><td>30</td><td>38</td><td>75</td></tr>
<tr><td>Site 2--Vaccinate</td><td>0</td><td>2</td><td>7</td><td>14</td><td>38</td></tr>
<tr><td>Site 2--Placebo</td><td>7</td><td>27</td><td>31</td><td>39</td><td>60</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>April 25, 2017</td></tr>
</table>

Table 1: Lung Scores across all litters

Site 1:	LLS (%)	
	Vaccinate	Placebo
	0	6
	0	7
	1	7
	1	10
	3	10
	3	15
	3	17
	4	20
	4	20
	4	21
	5	25
	6	27
	7	27
	7	28
	8	29
	8	29
	8	30
	8	31
	9	32
	10	32
	10	34
	11	35
	12	37
	15	38
	15	39
	17	40
	18	41
	20	46
	21	53
	24	58
	25	60
	37	75

Site 2:	LLS (%)	
	Vaccinate	Placebo
	0	7
	0	17
	0	22
	1	22
	1	23
	2	25
	2	25
	2	25
	2	27
	3	28
	4	28
	4	29
	5	29
	5	30
	5	31
	7	31
	7	31
	7	32
	7	33
	8	34
	8	34
	10	37
	13	37
	13	38
	15	40
	15	43
	15	43
	16	47
	16	48
	18	48
	23	49
	38	60

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 23-week duration of immunity against respiratory disease caused by PRRS virus (PRRSV)</td></tr>
<tr><td>Product Administration</td><td>1 ml dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>3-week-old pigs, 32 vaccinates and 30 controls</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged with PRRSV, 23 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 10 days post-challenge.</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 %.

Five-number summary of the LLS

<table><tr><th>Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr><tr><td>Vaccinate</td><td>0</td><td>1</td><td>4</td><td>8</td><td>19</td></tr><tr><td>Control</td><td>9</td><td>17</td><td>26</td><td>40</td><td>52</td></tr></table>
Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 15, 2020</td></tr>
</table>

Table 1: LUNG LESION SCORES (LLS)

Animal ID	Group	LLS (%)
470	vaccinate	0
503	vaccinate	0
507	vaccinate	0
513	vaccinate	0
517	vaccinate	0
534	vaccinate	0
546	vaccinate	0
469	vaccinate	1
478	vaccinate	1
521	vaccinate	1
547	vaccinate	1
531	vaccinate	2
542	vaccinate	2
500	vaccinate	3
526	vaccinate	3
532	vaccinate	3
468	vaccinate	4
465	vaccinate	5
479	vaccinate	5
487	vaccinate	5
523	vaccinate	6
462	vaccinate	7
483	vaccinate	7
481	vaccinate	8
511	vaccinate	8
535	vaccinate	10
515	vaccinate	12
541	vaccinate	12
508	vaccinate	14
473	vaccinate	15
480	vaccinate	16
520	vaccinate	19

Animal ID	Group	LLS (%)
548	control	9
509	control	10
476	control	11
484	control	12
527	control	12
522	control	14
537	control	14
486	control	17
489	control	17
533	control	18
524	control	19
536	control	20
540	control	20
518	control	22
543	control	24
461	control	27
516	control	27
519	control	31
504	control	32
530	control	32
466	control	40
467	control	40
472	control	40
471	control	43
460	control	44
477	control	44
505	control	46
512	control	49
502	control	50
499	control	52

<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 mL dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>677 pigs, 3 weeks of age (17-24 days) at 3 study sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (total 677 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Swelling</td><td>0</td></tr>
<tr><td>Lethargy</td><td>29</td></tr>
<tr><td>Poor feed conversion</td><td>8</td></tr>
<tr><td>Conjunctivitis</td><td>6</td></tr>
<tr><td>Loss of condition</td><td>6</td></tr>
<tr><td>Tachypnea</td><td>6</td></tr>
<tr><td>Arthritis</td><td>4</td></tr>
<tr><td>Cough</td><td>4</td></tr>
<tr><td>Death*</td><td>4</td></tr>
<tr><td>Dehydration</td><td>4</td></tr>
<tr><td>Lameness</td><td>4</td></tr>
<tr><td>Anorexia (a)</td><td>3</td></tr>
<tr><td>Diarrhea</td><td>3</td></tr>
<tr><td>Rhinitis</td><td>3</td></tr>
<tr><td>Trauma NOS (b)</td><td>2</td></tr>
<tr><td>Dermatitis and eczema</td><td>1</td></tr>
<tr><td>Respiratory tract disorder NOS</td><td>1</td></tr>
<tr><td>Weight loss</td><td>1</td></tr>
<tr><td>No adverse events</td><td>639</td></tr>
</table>
*Affirmed by licensee to have a cause other than vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>December 23, 2016</td></tr>
</table>