Summary of Studies Supporting USDA Product Licensure

Establishment Name	Medgene Labs
USDA Vet Biologics Establishment Number	474
Product Code	19A5.RA
True Name	Swine Influenza Vaccine, H3, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 03, 2023

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>Swine Influenza Vaccine, H3</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of Efficacy against swine influenza virus (H3)</td></tr>
<tr><td>Product Administration</td><td>2 doses, given intramuscularly, 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>3-4-week-old pigs, 30 vaccinates and 14 controls</td></tr>
<tr><td>Challenge Description</td><td>Swine Influenza Virus (A/Swine/IA/A01566613/2014-H3N2) was administered 14 days following 2nd vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were evaluated for clinical signs for 5 days post challenge. Lung lesions were evaluated at 5 days post challenge.</td></tr>
<tr><td>Results</td><td>Lung lesion scoring was performed 5 days post challenge and total lung lesion percentage was calculated for every animal.

5-number summary for Lung Lesion (%)

<table>
<tr><th>Treatment</th><th>n</th><th>Min</th><th>25th Pctl</th><th>Median</th><th>75th Pctl</th><th>Max</th></tr>
<tr><td>Controls</td><td>14</td><td>0.0</td><td>1.3</td><td>2.9</td><td>4.6</td><td>8.9</td></tr>
<tr><td>Vaccinates</td><td>30</td><td>0.0</td><td>0.0</td><td>0.2</td><td>1.3</td><td>4.3</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>June 28, 2019</td></tr>
</table>

Lung Lesion Scores (%), in order of rank:

Vaccinate	Control
0	0
0	0.5
0	0.825
0	1.2
0	1.425
0	1.625
0	2.2375
0	3.65
0	3.7
0	4.2625
0.05	4.725
0.05	7.7
0.1	7.8375
0.1	8.9375
0.2	
0.3	
0.3	
0.35	
0.35	
0.45	
0.45	
1.2375	
1.275	
1.3	
1.375	
2.3375	
2.4	
2.65	
2.8	
4.2875	

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under field conditions
Product Administration	2 doses, given intramuscularly, 3 weeks apart
Study Animals	690 pigs at 3 sites, 16-22 days-of-age
Challenge Description	Not applicable
Interval observed after challenge	Not applicable
Results	Pigs were observed immediately after each vaccination and daily through 14 days after the last vaccination.

Injection Site Reactions

Site	Total # of Animals	Maximum Size of Injection Site Reaction (cm)			No Injection Site Reaction
		<1.5	1.5-5.0	>5.0	
Site 1	230	2	0	0	228
Site 2	230	17	2	0	211
Site 3	230	41	0	0	189

Adverse Events

Clinical Observation	Number of Clinical Observations Post-Vaccination*		
	Site 1	Site 2	Site 3
Greasy Skin (Seborrhoea)	0	0	3
Head tilt-Neurologic Disorder (Centra Nervous System Disorder NOS)	0	1	0
Labored Breathing (Dyspnea)	0	1	0
Lameness	7	1	1
Leg Scrapes (limb non-weight bearing)	1	0	0

	Multiple localized swelling-not at injection site/Welts (Urticaria)	0	0	1
	Ataxia	0	2	0
	Anorexia	5	3	0
	Rectal Prolapse	0	1	0
	Scours (Diarrhea)	2	1	0
	Self-Trauma (Pruritus)	0	0	1
	Lethargy	0	0	1
	Unthrifty (Poor feed conversion)	1	0	8
	Vomiting (Digestive tract disorder)	1	0	0

*Include adverse events documented by the investigator as related to the test vaccine or were unknown as to whether they were related.

Additional adverse events affirmed by investigators to NOT be attributable to the product were death by humane euthanasia and found dead

USDA Approval Date	November 08, 2021