



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Huvepharma, Inc.
USDA Vet Biologics Establishment Number	605
Product Code	19A5.D3
True Name	Swine Influenza Vaccine, DNA
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ExactVac DNA - No distributor specified
Date of Compilation Summary	March 23, 2020

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.

Study Type	Efficacy																																																		
Pertaining to	Swine influenza virus																																																		
Study Purpose	Efficacy against H3N2 influenza																																																		
Product Administration	Two doses administered intramuscularly two weeks apart																																																		
Study Animals	Commercial pigs, 3 weeks of age, 13 vaccinates and 15 controls																																																		
Challenge Description	Swine influenza virus A/swine/SouthDakota/A01280095/2103 (H3N2) given 23 days after the final vaccination																																																		
Interval observed after challenge	Lungs evaluated 5 days after challenge																																																		
Results	<p>The percent of lung mass that was abnormal (consolidated) was calculated for each animal.</p> <p>Five tier summary of lung lesions</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Min</i></th> <th><i>Q1</i></th> <th><i>Med</i></th> <th><i>Q3</i></th> <th><i>Max</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>0.00</td> <td>0.45</td> <td>1.45</td> <td>2.74</td> <td>8.61</td> </tr> <tr> <td><i>Control</i></td> <td>0.60</td> <td>4.45</td> <td>6.39</td> <td>12.05</td> <td>13.95</td> </tr> </tbody> </table> <p>Lung consolidation scores (%), in order of rank</p> <table border="1"> <thead> <tr> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr><td>0.00</td><td>0.60</td></tr> <tr><td>0.00</td><td>0.90</td></tr> <tr><td>0.05</td><td>2.65</td></tr> <tr><td>0.45</td><td>4.19</td></tr> <tr><td>0.60</td><td>4.70</td></tr> <tr><td>1.38</td><td>5.65</td></tr> <tr><td>1.45</td><td>6.29</td></tr> <tr><td>1.50</td><td>6.39</td></tr> <tr><td>2.20</td><td>8.04</td></tr> <tr><td>2.74</td><td>10.94</td></tr> <tr><td>2.90</td><td>11.81</td></tr> <tr><td>7.13</td><td>12.29</td></tr> <tr><td>8.61</td><td>12.95</td></tr> <tr><td></td><td>13.56</td></tr> <tr><td></td><td>13.95</td></tr> </tbody> </table>	<i>Group</i>	<i>Min</i>	<i>Q1</i>	<i>Med</i>	<i>Q3</i>	<i>Max</i>	<i>Vaccinate</i>	0.00	0.45	1.45	2.74	8.61	<i>Control</i>	0.60	4.45	6.39	12.05	13.95	Vaccinates	Controls	0.00	0.60	0.00	0.90	0.05	2.65	0.45	4.19	0.60	4.70	1.38	5.65	1.45	6.29	1.50	6.39	2.20	8.04	2.74	10.94	2.90	11.81	7.13	12.29	8.61	12.95		13.56		13.95
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USDA Approval Date	December 28, 2017																																																		

Study Type	Safety																																																																																											
Pertaining to	All																																																																																											
Study Purpose	Demonstrate safety of product under typical use conditions.																																																																																											
Product Administration	Two doses administered intramuscularly two weeks apart.																																																																																											
Study Animals	672 pigs at 3 sites. Minimum age 3 weeks.																																																																																											
Challenge Description	Not applicable																																																																																											
Interval observed after challenge	Not applicable																																																																																											
Results	<p>Pigs were observed immediately after vaccination and weekly for three weeks after each vaccination.</p> <p>Injection Site Reactions</p> <table border="1"> <thead> <tr> <th rowspan="2">Site</th> <th rowspan="2">Total number animals</th> <th colspan="3">Maximum size of injection site reaction (cm)</th> <th rowspan="2">Not Palpable</th> <th rowspan="2">No injection site reaction</th> </tr> <tr> <th>< 1.5</th> <th>1.5 – 5.0</th> <th>> 5.0</th> </tr> </thead> <tbody> <tr> <td>Site 1</td> <td>202</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>202</td> </tr> <tr> <td>Site 2</td> <td>228</td> <td>9</td> <td>0</td> <td>0</td> <td>1</td> <td>218</td> </tr> <tr> <td>Site 3</td> <td>242</td> <td>2</td> <td>0</td> <td>0</td> <td>0</td> <td>240</td> </tr> </tbody> </table> <p>Injection site reactions were all resolved by 21 days after vaccination.</p> <p>Adverse Events</p> <table border="1"> <thead> <tr> <th rowspan="2">Clinical Observation</th> <th colspan="3">Number of clinical observations post-vaccination</th> </tr> <tr> <th>Site 1</th> <th>Site 2</th> <th>Site 3</th> </tr> </thead> <tbody> <tr> <td>Trachea hematoma</td> <td>0</td> <td>2</td> <td>0</td> </tr> <tr> <td>Death</td> <td>4</td> <td>1</td> <td>0</td> </tr> <tr> <td>Swollen joints/Arthritis</td> <td>1</td> <td>2</td> <td>0</td> </tr> <tr> <td>Decreased appetite</td> <td>15</td> <td>0</td> <td>0</td> </tr> <tr> <td>Dyspnea*</td> <td>18</td> <td>0</td> <td>0</td> </tr> <tr> <td>Lameness</td> <td>6</td> <td>0</td> <td>1</td> </tr> <tr> <td>Depression</td> <td>1</td> <td>0</td> <td>0</td> </tr> <tr> <td>Ataxia*</td> <td>1</td> <td>0</td> <td>0</td> </tr> <tr> <td>Abnormal breathing*</td> <td>2</td> <td>0</td> <td>0</td> </tr> <tr> <td>Anorexia</td> <td>15</td> <td>0</td> <td>0</td> </tr> <tr> <td>Diarrhea</td> <td>1</td> <td>0</td> <td>3</td> </tr> <tr> <td>Cough</td> <td>1</td> <td>0</td> <td>5</td> </tr> </tbody> </table>						Site	Total number animals	Maximum size of injection site reaction (cm)			Not Palpable	No injection site reaction	< 1.5	1.5 – 5.0	> 5.0	Site 1	202	0	0	0	0	202	Site 2	228	9	0	0	1	218	Site 3	242	2	0	0	0	240	Clinical Observation	Number of clinical observations post-vaccination			Site 1	Site 2	Site 3	Trachea hematoma	0	2	0	Death	4	1	0	Swollen joints/Arthritis	1	2	0	Decreased appetite	15	0	0	Dyspnea*	18	0	0	Lameness	6	0	1	Depression	1	0	0	Ataxia*	1	0	0	Abnormal breathing*	2	0	0	Anorexia	15	0	0	Diarrhea	1	0	3	Cough	1	0	5
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	Loss of condition	0	11	4
	Small, unthrifty	0	1	0
	Umbilical hernia	0	0	2
<p>*One pig observed with dyspnea, ataxia and abnormal breathing immediately after vaccination, all of which resolved without medical intervention within a few minutes. All other observations affirmed by licensee to be due to causes other than vaccination.</p>				
USDA Approval Date	August 28, 2019			