Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	49G6.2B
True Name	Parvovirus-Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FluSure XP FarrowSure Gold - No distributor specified
Date of Compilation Summary	November 28, 2022

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	*Erysipelothrix rhusiopathiae*
Study Purpose	Demonstrate effectiveness against *Erysipelothrix rhusiopathiae*
Product Administration	
Study Animals	Swine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 12, 2002

Study Type	Efficacy
Pertaining to	*Erysipelothrix rhusiopathiae*
Study Purpose	Demonstrate a duration of immunity of at least 18 weeks against *Erysipelothrix rhusiopathiae*
Product Administration	
Study Animals	Swine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	November 17, 2005

Study Type	Efficacy
Pertaining to	Swine Influenza Virus H1N1
Study Purpose	To demonstrate efficacy against respiratory disease due to Swine Influenza Virus H1N1
Product Administration	Intramuscular dose administered two weeks apart
Study Animals	Swine
Challenge Description	SIV H1N1 strain Minn 01-10597H1
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	01MAY2007

Study Type	Efficacy
Pertaining to	Swine Influenza A virus
Study Purpose	Efficacy against respiratory disease due to Swine Influenza A H1N1, H1N2, and H3N2
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	This product class allows the manufacturer to update microorganisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination challenge studies may not have been required for these updates.
USDA Approval Date	Apr 03 2015

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Swine Influenza</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease due to Swine Influenza Virus, H3N2</td></tr>
<tr><td>Product Administration</td><td>Intramuscular dose administered two weeks apart</td></tr>
<tr><td>Study Animals</td><td>Swine influenza virus serologically negative commercial pigs 3 weeks of age at administration, 20 vaccinates and 21 controls</td></tr>
<tr><td>Challenge Description</td><td>Influenza A/Swine/Indiana/853/2012 H3N2, administered 14 days after last vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 5 days. Lung lesions were evaluated 5 days after challenge</td></tr>
<tr><td>Results</td><td>Lung lesions was calculated with >5% lung lesions defined as a positive case

Five number summary of Lung Consolidation (%):
<table>
<tr><th>Treatment</th><th>n</th><th>Min</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max</th></tr>
<tr><td>Controls</td><td>21</td><td>1.4</td><td>12.0</td><td>16.5</td><td>19.9</td><td>34.5</td></tr>
<tr><td>Vaccinates</td><td>20</td><td>0</td><td>0.8</td><td>6.0</td><td>9.9</td><td>15.4</td></tr>
</table>

Individual animal data provided below:</td></tr>
<tr><td>USDA Approval Date</td><td>13JUN2016</td></tr>
</table>

Percentage of Total Lung with Lesions, in order of rank:

Control ID	Control % Lung Consolidation
118	1.40
108	8.75
180	9.90
147	10.00
185	11.45
131	12.00
178	13.25
111	15.00
167	15.00
122	16.25
143	16.50
134	17.00
126	17.75
177	19.50
113	19.75
169	19.90
136	20.50
188	23.25
102	24.75
140	28.50
103	34.50

Vaccinate ID	Vaccinate % Lung Consolidation
170	0.00
179	0.30
187	0.45
101	0.50
174	0.50
104	1.15
145	1.55
186	3.30
127	3.80
144	5.50
130	6.50
112	7.50
137	7.50
117	8.45
123	9.25
176	10.50
107	12.20
138	12.50
115	13.50
172	15.45

Study Type	Efficacy
Pertaining to	Swine Influenza Virus H3N2
Study Purpose	To demonstrate efficacy against respiratory disease due to Swine Influenza Virus H3N2
Product Administration	Intramuscular dose administered two weeks apart
Study Animals	Swine
Challenge Description	SIV H3N2 strain NADC 3
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	01MAY2007

Study Type	Efficacy
Pertaining to	*Leptospira canicola*
Study Purpose	Demonstrate effectiveness against *Leptospira canicola*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1978

Study Type	Efficacy
Pertaining to	*Leptospira grippotyphosa*
Study Purpose	Demonstrate effectiveness against *Leptospira grippotyphosa*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1978

Study Type	Efficacy
Pertaining to	*Leptospira hardjo*
Study Purpose	Demonstrate effectiveness against *Leptospira hardjo*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1978

Study Type	Efficacy
Pertaining to	*Leptospira icterohaemorrhagiae*
Study Purpose	Demonstrate effectiveness against *Leptospira icterohaemorrhagiae*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1978

Study Type	Efficacy
Pertaining to	*Leptospira pomona*
Study Purpose	Demonstrate effectiveness against *Leptospira pomona*
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 15, 1978

Study Type	Efficacy
Pertaining to	Porcine parvovirus
Study Purpose	Demonstrate effectiveness against porcine parvovirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	September 15, 1980

<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 under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses, 21 days apart, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>205 pre-breeding gilts, 18-20 weeks of age</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed immediately after vaccination and at least daily for 21 days after vaccination.
Injection sites were observed on days 1–3 and 10 following vaccination, and days 22–24 and 35 following re-vaccination.</td></tr>
<tr><td>Results</td><td><u>Clinical Observations*</u>

<table>
<tr><td></td><td>Vaccinates</td></tr>
<tr><td>Normal</td><td>202</td></tr>
<tr><td>Abscess on limb</td><td>1</td></tr>
<tr><td>Hernia</td><td>1</td></tr>
<tr><td>Swollen limb</td><td>1</td></tr>
</table>
*Other adverse events noted were lameness, enterocolitis, lung abscess, mesenteric edema, mesenteric torsion with chronic pleural lesions, cough, lethargy, pyrexia, and inappetence, however, they were all affirmed by the licensee to not be attributed to the vaccine.

<u>Injection Site Reactions</u>

<table>
<tr><td rowspan="2">Day</td><td>Vaccinates</td></tr>
<tr><td>Abnormal</td></tr>
<tr><td>1</td><td>2/205</td></tr>
<tr><td>2</td><td>1/205</td></tr>
<tr><td>3</td><td>0/205</td></tr>
<tr><td>10</td><td>0/205</td></tr>
<tr><td>22</td><td>9/203</td></tr>
<tr><td>23</td><td>2/203</td></tr>
<tr><td>24</td><td>1/203</td></tr>
<tr><td>35</td><td>0/202</td></tr>
</table>

Three vaccinated animals were removed from the study due to causes unrelated to vaccination.</td></tr>
<tr><td>USDA Approval Date</td><td>March 11, 2008</td></tr>
</table>

<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 under field conditions, including safety in pregnant animals</td></tr>
<tr><td>Product Administration</td><td>Two doses, 21 days apart, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>204 vaccinated pregnant sows or gilts and 104 control pregnant sows or gilts</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed immediately after vaccination and at least daily for 21 days after vaccination.
Injection sites were observed on days 1–3 and 9 following vaccination, and day 21 following re-vaccination.</td></tr>
<tr><td>Results</td><td>Clinical Observations*

<table>
<tr><td></td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>Normal</td><td>93</td><td>162</td></tr>
<tr><td>Abortion</td><td>5</td><td>0</td></tr>
<tr><td>Anorexia</td><td>4</td><td>25</td></tr>
<tr><td>Raised Lump</td><td>0</td><td>24</td></tr>
<tr><td>Redness/Swelling</td><td>0</td><td>6</td></tr>
</table>
*Pigs observed as abnormal may exhibit more than one clinical sign.

Injection Site Reactions

<table>
<tr><td></td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>1</td><td>0/104</td><td>2/204</td></tr>
<tr><td>2</td><td>0/104</td><td>18/204</td></tr>
<tr><td>3</td><td>0/104</td><td>35/204</td></tr>
<tr><td>9</td><td>0/104</td><td>1/204</td></tr>
<tr><td>21</td><td>0/104</td><td>0/204</td></tr>
</table>
Litter Details

<table>
<tr><td></td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>Piglets Born Alive</td><td>1129</td><td>2394</td></tr>
<tr><td>Stillborn Piglets</td><td>63</td><td>106</td></tr>
<tr><td>Low Viability Piglets</td><td>0</td><td>7</td></tr>
<tr><td>Mummified Piglets</td><td>91</td><td>149</td></tr>
</table>
Two vaccinated animals were removed from the study prior to farrowing due to causes unrelated to vaccination.</td></tr>
<tr><td>USDA Approval Date</td><td>March 11, 2008</td></tr>
</table>

<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 under field conditions, including safety in pregnant animals</td></tr>
<tr><td>Product Administration</td><td>Two doses, 21 days apart, administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>202 vaccinated pregnant sows or gilts and 101 control pregnant sows or gilts</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed immediately after vaccination and at least daily for 21 days after vaccination.
Injection sites were observed on days 1–3 and 9 following vaccination, and day 21 following re-vaccination.</td></tr>
<tr><td>Results</td><td>Clinical Observations*

<table>
<tr><td></td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>Normal</td><td>93</td><td>177</td></tr>
<tr><td>Anorexia</td><td>7</td><td>14</td></tr>
<tr><td>Raised Lump</td><td>1</td><td>9</td></tr>
<tr><td>Prolapse</td><td>0</td><td>1</td></tr>
<tr><td>Vaginal Discharge</td><td>1</td><td>3</td></tr>
</table>
*Pigs observed as abnormal may exhibit more than one clinical sign.

Injection Site Reactions

<table>
<tr><td>Day Post-Vaccination</td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>1</td><td>0/100**</td><td>6/202</td></tr>
<tr><td>2</td><td>0/100</td><td>34/202</td></tr>
<tr><td>3</td><td>0/100</td><td>22/202</td></tr>
<tr><td>9</td><td>0/100</td><td>1/202</td></tr>
<tr><td>21</td><td>0/100</td><td>0/202</td></tr>
</table>
**One control was mis-dosed and therefore removed from analysis.

Litter Details

<table>
<tr><td></td><td>Controls</td><td>Vaccinates</td></tr>
<tr><td>Piglets Born Alive</td><td>1170</td><td>2314</td></tr>
<tr><td>Stillborn Piglets</td><td>78</td><td>185</td></tr>
<tr><td>Low Viability Piglets</td><td>0</td><td>0</td></tr>
<tr><td>Mummified Piglets</td><td>28</td><td>36</td></tr>
</table></td></tr>
<tr><td>USDA Approval Date</td><td>March 11, 2008</td></tr>
</table>