Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4994.2D
True Name	Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FluSure XP/RespiSure1ONE/ER Bac Plus - No distributor specified
Date of Compilation Summary	June 21, 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 20 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 24, 1998

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	Two doses administered intramuscularly
Study Animals	Swine
Challenge Description	Minnesota SIV isolate 01-10597H1 (H1N1)
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	12FEB2002

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 short term efficacy after vaccination against respiratory disease due to Swine Influenza Virus H3N2
Product Administration	Two doses administered intramuscularly
Study Animals	Swine
Challenge Description	NADC SIV isolate 3 (H3N2)
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 15, 2001

Study Type	Efficacy
Pertaining to	Swine Influenza Virus H3N2
Study Purpose	To demonstrate efficacy 10 weeks after vaccination against respiratory disease due to Swine Influenza Virus H3N2
Product Administration	Two doses administered intramuscularly
Study Animals	Swine
Challenge Description	NADC Swine Influenza Virus Isolate 3 (H3N3)
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	21OCT2003

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae, Erysipelothrix rhusiopathiae,* and swine influenza virus
Study Purpose	Demonstrate lack of interference between swine influenza virus, *M. hyopneumoniae*, and *E. 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 05, 2001

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 8 weeks against *Mycoplasma hyopneumoniae*
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 18, 1999

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 18 weeks against *Mycoplasma hyopneumoniae*
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 18, 1999

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 25 weeks against *Mycoplasma hyopneumoniae*
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 14, 2001

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 23 weeks against *Mycoplasma hyopneumoniae*
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	May 10, 2000

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets
Product Administration	Two doses administered intramuscularly
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	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets
Product Administration	Two doses administered intramuscularly
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	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets
Product Administration	Two doses administered intramuscularly
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	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
Product Administration	Two doses administered intramuscularly
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	April 29, 2002

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
Product Administration	Two doses administered intramuscularly
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	April 29, 2002

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
Product Administration	Two doses administered intramuscularly
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	April 29, 2002