Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4993.20
True Name	Swine Influenza Vaccine, H1N1 & H3N2, Killed Virus, Erysipelothrix Rhusiopathiae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FluSure ER - Zoetis Japan Inc. FluSure/ER Bac Plus - No distributor specified Not Listed - No distributor specified
Date of Compilation Summary	February 16, 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.

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	*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	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 including clinical signs, lung lesions, viral shedding (numbers of animals and numbers of days), and viral persistence in the lung
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 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	Swine Influenza Virus H3N2
Study Purpose	To demonstrate short term efficacy after vaccination against respiratory disease due to Swine Influenza Virus H3N2 including clinical signs, lung lesions, viral shedding (numbers of animals and numbers of days), and viral persistence in the lung
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	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