Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2A41.00
True Name	Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	RespiSure/ER Bac Plus - No distributor specified
Date of Compilation Summary	September 29, 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	*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 effectiveness against *Mycoplasma hyopneumoniae*
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	June 04, 1990

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