Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19Q1.20
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive Form, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	December 09, 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	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRS disease
Product Administration	Administration of one dose intramuscularly
Study Animals	Ten gilts, divided into 5 vaccinates and 5 controls
Challenge Description	Pregnant gilts were challenged with PRRS virus 88 days after insemination
Interval observed after challenge	Through parturition for sow and piglet condition
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	July 8, 1996

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRS disease
Product Administration	Administration of one dose intramuscularly
Study Animals	12 pre-breeding sows, divided into 8 vaccinates and 4 controls
Challenge Description	Challenged with PRRS 118 days after vaccination (90 days of gestation)
Interval observed after challenge	Through parturition for sow and piglet condition
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	October 6, 1995

Study Type	Safety
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstrate safety of product in non-pregnant gilts/sows under typical field conditions
Product Administration	Administration of one dose intramuscularly
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	July 8, 1996

Study Type	Safety
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstrate safety of product in pregnant gilts / and or sows under typical field conditions
Product Administration	Administration of one dose intramuscularly
Study Animals	Six hundred and eleven sows/gilts, divided into 308 vaccinates and 303 controls
Challenge Description	NA
Interval observed after challenge	Sows/ gilts were examined two hours after treatment and once daily until farrowing. Piglets were observed daily up to weaning.
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	August 27, 2003