

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1891.20
True Name	Pseudorabies Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac Aujeszky MLV - Boehringer Ingelheim Animal Health (Thai) Ltd. Ingelvac Aujeszky MLV - Boehringer Ingelheim Animal Health Philippines, Inc. Ingelvac Aujeszky MLV - Boehringer Ingelheim Vetmedica GmbH Ingelvac Aujeszky MLV - INSUVECA Ingelvac Aujeszky MLV - No distributor specified Ingelvac PRV-G1 - No distributor specified
Date of Compilation Summary	September 29, 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.

Starday True o	Effective
Study Type	Efficacy
Pertaining to	Pseudorabies (Aujeszky's Disease)
Study Purpose	Demonstration of Efficacy against Pseudorabies
Product Administration	Intramuscular in pigs
Study Animals	Porcine
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 study data are published because this study was submitted to the USDA-APHIS prior to January 1, 2007 and APHIS only requires publication of the data submitted after this date.
USDA Approval Date	December 18, 1981

Study Type	Efficacy
Pertaining to	Pseudorabies (Aujeszky's Disease)
Study Purpose	Demonstration of Efficacy against Pseudorabies
Product Administration	Intranasal
Study Animals	Porcine
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 study data are published because this study was submitted to the USDA-APHIS prior to January 1, 2007 and APHIS only requires publication of the data submitted after this date.
USDA Approval Date	January 19, 1989

Study Type	Safety
Pertaining to	Pseudorabies vaccine
Study Purpose	To demonstrate safety under field conditions
Product Administration	Piglets, gilts, sows, and boars
Study Animals	Porcine
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 11, 1992

Study Type	Safety
Pertaining to	Pseudorabies
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	Intranasal
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	January 19, 1989