Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2652.00
True Name	Haemophilus Parasuis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac HP-1 - Boehringer Ingelheim (Thai) Ltd. Ingelvac HP-1 - Boehringer Ingelheim Animal Health (Thai) Ltd. Ingelvac HP-1 - Boehringer Ingelheim Animal Health Mexico Ingelvac HP-1 - Boehringer Ingelheim Animal Health Philippines, Inc. Ingelvac HP-1 - Boehringer Ingelheim Animal Health do Brasil Ltda Ingelvac HP-1 - Boehringer Ingelheim Vetmedica GmbH Ingelvac HP-1 - No distributor specified Ingelvac HP-1 - PT Boehringer Ingelheim Indonesia
Date of Compilation Summary	November 19, 2019

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	Haemophilus Parasuis Bacterin
Study Purpose	Demonstration of Efficacy against Glasser's Disease
Product Administration	2 mL intramuscular in pigs 3 weeks of age or older, with a booster 2 mL IM dose 2 - 3 weeks later
Study Animals	Porcine
Challenge Description	Virulent *Haemophilus parasuis* given IM 12 days after the 2nd vaccination
Interval observed after challenge	7 days following administration of 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 16, 1992

Study Type	Efficacy
Pertaining to	Haemophilus Parasuis Bacterin
Study Purpose	Demonstration of Duration of Immunity against Glasser's Disease
Product Administration	Intramuscular in pigs 3 - 4 weeks of age or older
Study Animals	Porcine
Challenge Description	Virulent *Haemophilus parasuis* challenge administered 132 days after vaccination
Interval observed after challenge	7 days following administration of 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	April 26, 2001

Study Type	Safety
Pertaining to	Haemophilus Parasuis Bacterin
Study Purpose	Demonstration of Safety under Field Conditions
Product Administration	Intramuscular in pigs 3 - 4 weeks of age, with a booster IM dose 2 - 4 weeks later
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	February 22, 1993