Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2663.00
True Name	Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bar Somnus/Lepto-5 - No distributor specified
Date of Compilation Summary	November 27, 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	*Haemophilus somnus*
Study Purpose	Demonstration of efficacy against *Haemophilus somnus*
Product Administration	
Study Animals	Bovine
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	May 5, 1981

Study Type	Efficacy
Pertaining to	*Leptospira canicola*
Study Purpose	Demonstration of efficacy against leptospirosis caused by *Leptospira canicola*
Product Administration	
Study Animals	Bovine and 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	July 14, 1981

Study Type	Efficacy
Pertaining to	*Leptospira grippotyphosa*
Study Purpose	Demonstration of efficacy against leptospirosis caused by *Leptospira grippotyphosa*
Product Administration	
Study Animals	Bovine and 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	July 14, 1981

Study Type	Efficacy
Pertaining to	*Leptospira hardjo*
Study Purpose	Demonstration of efficacy against leptospirosis caused by *Leptospira hardjo*
Product Administration	
Study Animals	Bovine and 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	July 14, 1981

Study Type	Efficacy
Pertaining to	*Leptospira icterohaemorrhagiae*
Study Purpose	Demonstration of efficacy against leptospirosis caused by *Leptospira icterohaemorrhagiae*
Product Administration	
Study Animals	Bovine and 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	July 14, 1981

Study Type	Efficacy
Pertaining to	*Leptospira pomona*
Study Purpose	Demonstration of efficacy against leptospirosis caused by *Leptospira pomona*
Product Administration	
Study Animals	Bovine and 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	July 14, 1981

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Safety by intramuscular route in cattle
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.