Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	44M5.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Campylobacter Fetus-Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vira Shield 6 + VL5 HB Somnus - Elanco US Inc.
Date of Compilation Summary	May 19, 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	Bovine Virus Diarrhea (BVD)
Study Purpose	To demonstrate effectiveness against Bovine Virus Diarrhea Type 1b
Product Administration	
Study Animals	Bovine
Challenge Description	BVD isolate NY-1, BVD1b
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 require publication of data submitted after that date.
USDA Approval Date	July 16, 2003

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD)
Study Purpose	To demonstrate effectiveness against Bovine Virus Diarrhea Type 2a
Product Administration	
Study Animals	Bovine
Challenge Description	BVD isolate 890, Type BVD2a
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 require publication of data submitted after that date.
USDA Approval Date	November 3, 1998

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea
Study Purpose	To demonstrate effectiveness against Bovine Virus Diarrhea Type 2a at 11 months post-vaccination
Product Administration	
Study Animals	Bovine
Challenge Description	BVD Isolate 890, Type BVD2a
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 require publication of data submitted after that date.
USDA Approval Date	September 24, 1996

Study Type	Efficacy
Pertaining to	*Campylobacter fetus*
Study Purpose	To demonstrate effectiveness against *Campylobacter fetus*
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 require publication of data submitted after that date.
USDA Approval Date	January 14, 1986

Study Type	Efficacy
Pertaining to	*Campylobacter fetus*
Study Purpose	To demonstrate effectiveness against *Campylobacter fetus* for one year duration of immunity
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 require publication of data submitted after that date.
USDA Approval Date	March 15, 1989

Study Type	Efficacy
Pertaining to	Bovine Rhinotracheitis
Study Purpose	To demonstrate effectiveness against Bovine Rhinotracheitis.
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 require publication of data submitted after that date.
USDA Approval Date	October 22, 1986

Study Type	Efficacy
Pertaining to	*Haemophilus somnus*
Study Purpose	To demonstrate effectiveness 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 require publication of data submitted after that date.
USDA Approval Date	August 2, 1988

Study Type	Efficacy
Pertaining to	*Leptospira canicola, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, Leptospira pomona*
Study Purpose	To demonstrate effectiveness against *Leptospira spp.*
Product Administration	
Study Animals	Bovine, 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 require publication of data submitted after that date.
USDA Approval Date	March 18, 1983

Study Type	Efficacy
Pertaining to	*Leptospira hardjo* type *hardjo-bovis*
Study Purpose	To demonstrate effectiveness against *Leptospira hardjo* type *hardjo-bovis*
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 require publication of data submitted after that date.
USDA Approval Date	July 24, 2001 / November 9, 2001

Study Type	Efficacy
Pertaining to	Bovine Parainfluenza Type 3
Study Purpose	To demonstrate effectiveness against Bovine Parainfluenza Type 3.
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 require publication of data submitted after that date.
USDA Approval Date	March 12, 1987 (License Issued)

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus
Study Purpose	To demonstrate effectiveness against Bovine Respiratory Syncytial Virus
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 require publication of data submitted after that date.
USDA Approval Date	December 18, 1987

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Safety by IM route in healthy cattle, including pregnant cows and heifers
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.