Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	44B6.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vira Shield 6+ L5 - Elanco US Inc. Vira Shield 6+VL5 - Elanco US Inc.
Date of Compilation Summary	June 23, 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	*Leptospira canicola, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, Leptospira pomona*
Study Purpose	To demonstrate effectiveness against *Leptospira spp.*
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 18, 1983

Study Type	Efficacy
Pertaining to	*Leptospira* Hardjo (type Hardjoprajitno)
Study Purpose	To demonstrate effectiveness against *Leptospira* Hardjo
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 18, 1983

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
Study Purpose	To demonstrate safety under typical field conditions
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	April 16, 2003

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine, including pregnant cows and heifers
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. However, study data are not available.