Summary of Studies Supporting USDA Product Licensure

Establishment Name	Bimeda Biologicals, Inc.
USDA Vet Biologics Establishment Number	290
Product Code	43S5.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Killed Virus, Haemophilus Somnus-Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Pro-Bac 4 + IBRk & BVDk with Reveal ATS - No distributor specified Super Poly-Bac B + IBRk & BVDk - No distributor specified
Date of Compilation Summary	January 27, 2021

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 Viral Diarrhea Virus (BVDV) Type 1
Study Purpose	Efficacy against BVDV Type 1
Product Administration	Subcutaneous
Study Animals	
Challenge Description	BVDV-1 CHV New York-1
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	September 16, 1999

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR
Product Administration	
Study Animals	
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 7, 1998

Study Type	Efficacy
Pertaining to	Haemophilus Somnus
Study Purpose	Demonstrate efficacy against Haemophilus Somnus
Product Administration	
Study Animals	
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	October 4, 1990

Study Type	Efficacy
Pertaining to	Mannheimia Haemolytica A6
Study Purpose	Efficacy against Mannheimia Haemolytica A6
Product Administration	
Study Animals	
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 19, 1999

Study Type	Efficacy
Pertaining to	Mannheimia Haemolytica
Study Purpose	Efficacy against respiratory disease due to Mannheimia Haemolytica A1
Product Administration	
Study Animals	
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	August 20, 1982

Study Type	Efficacy
Pertaining to	Pasteurella Multocida
Study Purpose	Demonstrate efficacy against Pasteurella Multocida
Product Administration	
Study Animals	
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	August 20, 1982

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	
Study Animals	
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 26, 2000