Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1121.31
True Name	Bovine Rhinotracheitis-Parainfluenza 3 Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis Nasalgen IP - Merck Animal Health Nasalgen IP - Intervet Mexico S.A. de C.V. - Merck Sharpe and Dohme (MSD) Nasalgen IP - Merck Animal Health Nasalgen IP - No distributor specified
Date of Compilation Summary	May 12, 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	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against disease caused by IBR
Product Administration	Intranasal
Study Animals	Cattle
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	March 30, 1998

Study Type	Efficacy
Pertaining to	Parainfluenza Virus 3 (PI3)
Study Purpose	To demonstrate effectiveness against disease caused by PI3
Product Administration	Intranasal
Study Animals	Cattle
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	September 14, 1983

Study Type	Safety
Pertaining to	
Study Purpose	Safety by intranasal administration to pregnant cows and calves nursing pregnant cows
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	March 29, 2005

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Intranasal
Study Animals	Cattle
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	March 9, 1984