



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1071.20
True Name	Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	December 20, 2018

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bovine Rhinotracheitis (IBR)
<b>Study Purpose</b>	Demonstration of efficacy against IBR (respiratory disease)
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	September 9, 1994

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Parainfluenza Type 3 (PI <sub>3</sub> )
<b>Study Purpose</b>	Demonstration of efficacy against PI <sub>3</sub>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	June 14, 1994

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Respiratory Syncytial Virus (BRSV)
<b>Study Purpose</b>	Demonstration of efficacy against BRSV
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	June 14, 1994

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	September 9, 1994

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine: pregnant cows and calves nursing pregnant cows provided the cows were vaccinated pre-breeding
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	December 6, 2005