Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	12M5.01
True Name	Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard & Variant, Mass Type, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Breedervac-8 - MSD Salud Animal Columbia S.A.S. - Merck Sharpe and Dohme (MSD) Breedervac-IV-Plus - Intervet Mexico S.A. de C.V. Breedervac-IV-Plus - Merck Animal Health
Date of Compilation Summary	October 21, 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 Bursal Disease (IBD), Standard Strain
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against IBD, Standard strain to progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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 15, 1987

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease (IBD), Delaware Variant A Strain
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against IBD, Delaware Variant A strain, to progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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 15, 1987

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease (IBD), Delaware Variant E Strain
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against IBD, Delaware Variant E strain, in progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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 29, 1988

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease (IBD), GLS-5 Strain
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against IBD, GLS-5 strain, to progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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	February 8, 1991

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease (IBD), Standard & Variant Strains
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against IBD, standard and variant strains, to progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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	May 8, 1992

Study Type	Efficacy
Pertaining to	Infectious Bronchitis Virus (IBV), Massachusetts Type
Study Purpose	To demonstrate effectiveness against IBV, Massachusetts Type.
Product Administration	Intramuscular
Study Animals	Chickens
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	May 8, 1992

Study Type	Efficacy
Pertaining to	Infectious Bronchitis Virus (IBV), Massachusetts Type and Newcastle Disease Virus (NDV)
Study Purpose	To demonstrate effectiveness against IBV, Massachusetts Type, and NDV.
Product Administration	Subcutaneous
Study Animals	Chickens
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. Study data, however, are no longer available.
USDA Approval Date	May 8, 1992

Study Type	Efficacy
Pertaining to	Newcastle Disease Virus (NDV)
Study Purpose	To demonstrate effectiveness against NDV.
Product Administration	Intramuscular
Study Animals	Chickens
Challenge Description	NDV Texas GB strain
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 30, 1982

Study Type	Efficacy
Pertaining to	Avian Reovirus
Study Purpose	To demonstrate effectiveness in chickens to provide passive immunity against malabsorption caused by Avian Reovirus to progeny.
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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	November 17, 1983

Study Type	Efficacy
Pertaining to	Avian Reovirus
Study Purpose	To demonstrate effectiveness against tenosynovitis caused by avian reovirus
Product Administration	Intramuscular
Study Animals	Chickens
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	November 17, 1983

Study Type	Efficacy
Pertaining to	Avian Reovirus
Study Purpose	To demonstrate effectiveness against tenosynovitis caused by Avian Reovirus.
Product Administration	Subcutaneous
Study Animals	Chickens
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. Study data, however, are no longer available.
USDA Approval Date	March 23, 1994

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	Subcutaneous, Intramuscular
Study Animals	Chickens
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	January 3, 1985