



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	12L1.00
True Name	Bursal Disease Vaccine, Variant, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	89/03 - No distributor specified
Date of Compilation Summary	October 18, 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 and Variant Strains
Study Purpose	To demonstrate effectiveness against IBD, standard and variant strains.
Product Administration	<i>In Ovo</i>
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	March 8, 2001

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease (IBD), Standard and Variant Strains
Study Purpose	To demonstrate effectiveness against IBD, standard and variant strains.
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. 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 30, 1992

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
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. 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 28, 1993

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	<i>In Ovo</i>
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 23, 2002