



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1271.41
True Name	Bursal Disease Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Intervet Argentina S.A. - Merck Sharpe and Dohme (MSD) Merck Animal Health Univax 2S - MSD Salud Animal Columbia S.A.S. Univax Plus - Abdulrehman Algosabi GTC (Saudi Arabia) Univax Plus - Intervet Argentina S.A. Univax Plus - Intervet Argentina S.A. - Merck Sharpe and Dohme (MSD) Univax Plus - Merck Animal Health Univax Plus - No distributor specified
Date of Compilation Summary	October 28, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease (IBD), Standard Strain
<b>Study Purpose</b>	To demonstrate effectiveness against IBD, standard strain.
<b>Product Administration</b>	Drinking Water
<b>Study Animals</b>	Chickens
<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>	October 26, 1989

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease (IBD), Variant Strain
<b>Study Purpose</b>	To demonstrate effectiveness against IBD, variant strain.
<b>Product Administration</b>	Drinking Water
<b>Study Animals</b>	Chickens
<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>	July 18, 1994

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To demonstrate safety of product under typical field conditions
<b>Product Administration</b>	Drinking Water
<b>Study Animals</b>	Chickens
<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 5, 2001