



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1271.17
True Name	Bursal Disease Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Clonevac D-78 - Merck Animal Health Clonevac D-78 - No distributor specified Merck Animal Health
Date of Compilation Summary	November 23, 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 29, 1981

<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>	Coarse Spray
<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. Study data, however, are no longer available.
<b>USDA Approval Date</b>	January 16, 1984

<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>	Coarse Spray
<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. Study data, however, are no longer available.
<b>USDA Approval Date</b>	May 11, 1982

<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>	May 11, 1982