

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	48D6.10
True Name	Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus, Salmonella Enteritidis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	BRON-NEWCAVAC-SE - Merck Animal Health BRON-NEWCAVAC-SE - 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
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Pertaining to	Infectious Bronchitis Disease (IBD), Massachusetts Type,
	and Newcastle Disease (NDV)
Study Purpose	To demonstrate effectiveness against IBD, Massachusetts Type,
v I	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. 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 25, 2001

Study Type	Efficacy
Pertaining to	Salmonella enteritidis (Phage Types 4 and 8)
Study Purpose	To demonstrate effectiveness against S. enteritidis (Phage
	Types 4 and 8) in internal organs including the reproductive tract
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 25, 2001

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Study Type	Efficacy
Pertaining to	Salmonella enteritidis (Phage Type 13a)
Study Purpose	To demonstrate effectiveness against S. enteritidis (Phage
	Type 13a) in internal organs including the reproductive tract
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 25, 2001

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	October 7, 2002