



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1231.21
True Name	Bronchitis Vaccine, Ark Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	June 04, 2019

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	Avian infectious bronchitis virus, Arkansas type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus, Arkansas type
Product Administration	Coarse spray
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	November 21, 1983

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Arkansas type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus, Arkansas type
Product Administration	
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 18, 1988

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Arkansas type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus, Arkansas type
Product Administration	Coarse aerosol spray
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 21, 1983

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Coarse spray, drinking water, and coarse aerosol spray
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	July 18, 1983