

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1233.10
True Name	Bronchitis Vaccine, Mass Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 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.

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Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus,
	Massachusetts type
Product Administration	Eyedrop at day-of-age
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	August 9, 1993

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Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Efficacy against avian infectious bronchitis virus, Massachusetts
	type
Product Administration	Eyedrop vaccination
Study Animals	Chickens at day-of-age
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	1993

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Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Efficacy against avian infectious bronchitis virus, Massachusetts
	type
Product Administration	Coarse spray
Study Animals	Chickens at day-of-age
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 25, 1982

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Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis,
	Massachusetts type
Product Administration	Drinking water administration
Study Animals	Chickens at 14 days of age
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 2, 1984

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Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Eyedrop at day-of-age
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	August 25, 1993

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Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Coarse spray at day-of-age
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	1981

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Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Drinking water administration
Study Animals	Chickens 10-14 days of age
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	1981

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