



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1771.11
True Name	Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Boehringer Ingelheim S.A. Gallivac La Sota Mass - No distributor specified LaSota MASS BLEN - Boehringer Ingelheim Animal Health (Thai) Ltd. LaSota MASS BLEN - No distributor specified
Date of Compilation Summary	January 26, 2020

**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 bronchitis virus, Massachusetts type
<b>Study Purpose</b>	Demonstrate efficacy against Infectious Bronchitis, Massachusetts type
<b>Product Administration</b>	Eyedrop
<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 9, 1993

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Avian infectious bronchitis virus, Massachusetts type
<b>Study Purpose</b>	Demonstrate efficacy against avian infectious bronchitis virus, Massachusetts type
<b>Product Administration</b>	Coarse aerosol spray at 14 days of age
<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>	March 17, 1982

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle Disease
<b>Product Administration</b>	Coarse aerosol 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. 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>	March 7, 1983

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle Disease
<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>	February 4, 1987

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle Disease
<b>Product Administration</b>	Eyedrop
<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 9, 1993

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	Eyedrop
<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>	August 25, 1993



<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under 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. Study data, however, are no longer available.
<b>USDA Approval Date</b>	May 17, 1984

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	Coarse aerosol 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 17, 1984