

## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1721.11
True Name	Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Lasota BLEN - No distributor specified Newcastle LaSota - Boehringer Ingelheim Animal Health do Brasil Ltda
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.

Study Type	Efficacy
Pertaining to	Newcastle Disease
Study Purpose	Demonstrate efficacy against Newcastle Disease
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	March 7, 1983

Study Type	Efficacy
Pertaining to	Newcastle Disease
Study Purpose	Demonstrate efficacy against Newcastle Disease
Product Administration	Drinking water
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 4, 1987

Study Type	Efficacy
Pertaining to	Newcastle Disease
Study Purpose	Demonstrate efficacy against Newcastle Disease
Product Administration	Eyedrop
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	June 2, 1992

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Eyedrop
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

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	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. 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	April 25, 1983