



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1771.18
True Name	Newcastle-Bronchitis Vaccine, B1 Type, LaSota Strain, Mass Type, Live Virus
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro ND-IB Sohol - EURL Provast - Lohmann Animal Health International AviPro ND-IB Sohol - Elanco Animal Health - Lohmann Animal Health International AviPro ND-IB Sohol - Encipharm Ltda. AviPro ND-IB Sohol - Ilender Peru S.A. AviPro ND-IB Sohol - Lohmann Animal Health International AviPro ND-IB Sohol - Lohmann Saude Animal Ltda AviPro ND-IB Sohol - No distributor specified AviPro ND-IB Sohol - TADEC CIA Ltda Lohmann Animal Health International
Date of Compilation Summary	December 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	Infectious bronchitis virus, Mass. type
Study Purpose	To demonstrate immunogenicity of Infectious bronchitis virus, Mass. Type, Holland strain
Product Administration	Drinking water, intraocular, aerosol spray
Study Animals	Chicken
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	May 10, 1978

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Mass. type
Study Purpose	To demonstrate efficacy against Infectious bronchitis virus
Product Administration	Intranasal
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV), B1 type, LaSota strain
Study Purpose	To demonstrate efficacy against NDV
Product Administration	Eyedrop, Drinking water, Aerosol spray
Study Animals	Chicken
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 10, 1983

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV), B1 type, LaSota strain
Study Purpose	To demonstrate efficacy against NDV
Product Administration	Intranasal
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Drinking water
Study Animals	Chicken
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 27, 1978

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Aerosol spray, Intranasal, Intraocular
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.