



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1785.11
True Name	Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	<p>AviPro 201 ND-IB - Elanco Animal Health - Lohmann Animal Health International</p> <p>AviPro 201 ND-IB - Ilender Peru S.A.</p> <p>AviPro 201 ND-IB - Lohmann Animal Health International</p> <p>AviPro 201 ND-IB - No distributor specified</p> <p>AviPro 201 ND-IB - TADEC CIA Ltda</p>
Date of Compilation Summary	April 09, 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.

Study Type	Efficacy
Pertaining to	Infectious bronchitis
Study Purpose	To demonstrate efficacy
Product Administration	Subcutaneous injection
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	January 25, 1988

Study Type	Efficacy
Pertaining to	Infectious bronchitis
Study Purpose	To demonstrate efficacy in field and lack of interference
Product Administration	Subcutaneous injection
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	January 25, 1988

Study Type	Efficacy
Pertaining to	Newcastle Disease
Study Purpose	To demonstrate efficacy in field and lack of interference
Product Administration	Subcutaneous injection
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	January 25, 1988

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
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	January 25, 1988