Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	12M5.01
True Name	Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard & Variant, Mass Type, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 431 ND-IB-BD3-REO - Bio Pharma Trading Co. AviPro 431 ND-IB-BD3-REO - EURL Provast AviPro 431 ND-IB-BD3-REO - Elanco Philippines, Inc - Elanco US Inc. AviPro 431 ND-IB-BD3-REO - Elanco Salud Animal, S.A. de C.V. AviPro 431 ND-IB-BD3-REO - Elanco Saude Animal Ltda. (Brazil) - Elanco US Inc. AviPro 431 ND-IB-BD3-REO - Elanco US Inc. AviPro 431 ND-IB-BD3-REO - Eli Lilly Philippines, Inc. AviPro 431 ND-IB-BD3-REO - Ilender Bolivia S.A. AviPro 431 ND-IB-BD3-REO - International Science Solution Co. LTD. AviPro 431 ND-IB-BD3-REO - No distributor specified
Date of Compilation Summary	August 30, 2021

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 bursal disease virus, variant strain
Study Purpose	To demonstrate protection of progeny against variant infectious bursal disease
Product Administration	Subcutaneous injection to breeder chickens
Study Animals	Chickens
Challenge Description	Delaware variant 1084E strain, Type 1
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	November 16, 1992

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus
Study Purpose	To demonstrate protection of progeny against standard infectious bursal disease
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	September 28, 1988

Study Type	Efficacy
Pertaining to	Infectious bronchitis virus, Mass. type
Study Purpose	To demonstrate efficacy
Product Administration	Subcutaneous injection
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. Study data, however, are no longer available.
USDA Approval Date	October 26, 1990

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	To demonstrate efficacy against Newcastle disease
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	September 28, 1988

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	To demonstrate efficacy against malabsorption syndrome caused by avian reovirus
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	September 28, 1988

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	To demonstrate efficacy against malabsorption syndrome caused by avian reovirus in progeny when product administered to hens
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	September 28, 1988

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	To demonstrate efficacy against tenosynovitis caused by avian reovirus in progeny when product administered to hens
Product Administration	Subcutaneous
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	October 11, 1983

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
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. Study data, however, are no longer available.
USDA Approval Date	October 26, 1998