Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	12D5.04
True Name	Bursal Disease-Reovirus Vaccine, Standard & Variant, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 226 BTO2-REO - Elanco Salud Animal, S.A. de C.V. AviPro 226 BTO2-REO - Elanco US Inc. AviPro 226 BTO2-REO - J. Orbe Asesores S.A.C. AviPro 226 BTO2-REO - Laboratories Bimex SRL AviPro 226 BTO2-REO - No distributor specified
Date of Compilation Summary	February 22, 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
Study Purpose	To demonstrate protection of progeny against type 1 infectious bursal disease, standard and variant strains
Product Administration	Subcutaneous injection to breeder chickens
Study Animals	
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 30, 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus (IBDV)
Study Purpose	To demonstrate efficacy against IBDV, AL-2 variant
Product Administration	One dose administered subcutaneously
Study Animals	20 vaccinates and 10 controls, unprimed chickens
Challenge Description	All chickens were challenged four weeks after vaccination with IBDV AL-2 variant.
Interval observed after challenge	One week post-challenge all chickens were weighed, necropsied, and the bursa weight determined.
Results	The ratio of the bursa weight over body weight was compared between the treatment groups. Raw Data is listed in the table below.
USDA Approval Date	October 1, 2009

Vaccinates			
Chicken	Body Weight (g)	Bursal Weight (g)	Bursal / Body Wt. (g)
1	680	1.15	0.001691176
2	642	1.25	0.00194704
3	696	3.21	0.004612069
4	824	1.46	0.001771845
5	806	1.26	0.001563275
6	670	2.34	0.003492537
7	588	1.37	0.002329932
8	664	1.56	0.002349398
9	600	1.42	0.002366667
10	556	2.32	0.004172662
11	602	2.54	0.004219269
12	740	1.99	0.002689189
13	738	2.26	0.003062331
14	726	2.93	0.004035813
15	670	1.85	0.002761194
16	550	1.22	0.002218182
17	738	2.86	0.003875339
18	652	1.31	0.002009202
19	582	1.61	0.002766323
20	638	1.42	0.002225705

Controls			
Chicken	Body Weight (g)	Bursal Weight (g)	Bursal / Body Wt. (g)
1	754	1.21	0.001604775
2	628	0.64	0.001019108
3	666	0.8	0.001201201
4	766	1.25	0.001631854
5	688	0.94	0.001366279
6	810	1	0.001234568
7	662	0.8	0.001208459
8	774	0 .8	0.001033592
9	702	1.13	0.001609687
10	691	0.91	0.001316932

Study Type	Efficacy
Pertaining to	Reovirus
Study Purpose	To demonstrate protection of progeny against malabsorption caused by Reovirus
Product Administration	Subcutaneous injection to breeder chickens
Study Animals	
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 30, 1995

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	March 22, 1984

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	Efficacy
Pertaining to	Reovirus
Study Purpose	To demonstrate protection of progeny against tenosynovitis caused by Reovirus
Product Administration	Subcutaneous injection to breeder chickens
Study Animals	
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 30, 1995

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
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	December 8, 1995