



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Huvepharma, Inc.
USDA Vet Biologics Establishment Number	605
Product Code	1A15.00
True Name	Avian Polyomavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PSITTIMUNE APV - Creative Science, LLC
Date of Compilation Summary	February 02, 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	Avian Polyomavirus (APV)
Study Purpose	Demonstrate efficacy in psittacines against APV
Product Administration	First dose given by subcutaneous injection at 35 days of age; second vaccination 2-3 weeks following the first vaccination
Study Animals	Quaker Parakeets and Cockatiels
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 28, 2001

Study Type	Efficacy
Pertaining to	Avian Polyomavirus (APV)
Study Purpose	Demonstrate duration of immunity of at least one year in psittacines against APV
Product Administration	First dose given by subcutaneous injection in adult budgerigars; second vaccination 2-3 weeks following the first vaccination
Study Animals	Budgerigars
Challenge Description	73 weeks after the second vaccination administration
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 28, 2001

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under typical use conditions
Product Administration	
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. Study data, however, are no longer available.
USDA Approval Date	December 6, 1995