

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	16D5.20
True Name	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Fel-O-Vax PCT - No distributor specified Fel-O-Vax PCT - Zoetis (Shanghai) Animal Health - Elanco US Inc. Fel-O-Vax PCT - Zoetis Inc Elanco US Inc.
Date of Compilation Summary	February 14, 2022

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	Feline Calicivirus
Study Purpose	To demonstrate effectiveness against respiratory disease due to
	feline calicivirus
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. 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 1, 1979 (license received)

Study Type	Efficacy
	Feline Rhinotracheitis (FVR)
Pertaining to	
Study Purpose	To demonstrate effectiveness against Feline Rhinotracheitis
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. 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 1, 1979 (license received)

Study Type	Efficacy
Pertaining to	Feline Panleukopenia Virus
Study Purpose	To demonstrate effectiveness against Feline Panleukopenia Virus
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. 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 1, 1979 (license received)

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Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate Safety of product under typical use conditions
Product Administration	
Study Animals	
Challenge Description	NA
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 1, 1979 (license received)