Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1905.20
True Name	Rabies Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

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	Rabies
Study Purpose	Demonstrate efficacy against rabies thirty-seven months after vaccination to establish a 3 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to Intramuscular (IM) route of administration. 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 25, 1986

Study Type	Efficacy
Pertaining to	Rabies
Study Purpose	Demonstrate efficacy against rabies thirty-six months after vaccination to establish 3 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Cats
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to Intramuscular (IM) route of administration. 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 25, 1986

Study Type	Efficacy
Pertaining to	Rabies
Study Purpose	Demonstrate efficacy against rabies sixteen months after vaccination to establish 1 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Cattle
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to Intramuscular (IM) route of administration. 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 16, 1983

Study Type	Efficacy
Pertaining to	Rabies
Study Purpose	Demonstrate efficacy against rabies thirty-six months after vaccination and establish 3 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Sheep
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to Intramuscular (IM) route of administration. 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 16, 1983

Study Type	Efficacy
Pertaining to	Rabies
Study Purpose	Demonstrate efficacy against rabies sixteen months after vaccination to establish 1 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Horses
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to Intramuscular (IM) route of administration. 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 13, 1984

Study Type	Efficacy
Pertaining to	Rabies
Study Purpose	Demonstrate efficacy against rabies thirteen months after vaccination to establish 1 year revaccination interval
Product Administration	Subcutaneously (SQ)
Study Animals	Ferrets
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 6, 1989

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	Dogs
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 18, 1983

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	Cats
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	1983

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ)
Study Animals	Ferrets
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 5, 1990

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	Cattle, sheep
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	March 16, 1983

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	Horses
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	January 13, 1984