



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	10M1.10
True Name	Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Boehringer Ingelheim Animal Health do Brasil Ltda Gallivac AE + FP - No distributor specified PT BLEN - Boehringer Ingelheim Animal Health Mexico Poxiblen - Boehringer Ingelheim Animal Health do Brasil Ltda
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	Avian encephalomyelitis
Study Purpose	Demonstrate efficacy against avian encephalomyelitis
Product Administration	Wing web stab
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. 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	August 13, 1990

Study Type	Efficacy
Pertaining to	Avian encephalomyelitis
Study Purpose	Demonstrate efficacy against avian encephalomyelitis
Product Administration	wing web stab
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. 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 22, 1978

Study Type	Efficacy
Pertaining to	Fowl pox
Study Purpose	Demonstrate efficacy against fowl pox
Product Administration	Wing web stab
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. 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, 1997

Study Type	Efficacy
Pertaining to	Fowl pox
Study Purpose	Demonstrate efficacy against fowl pox
Product Administration	Wing web stab
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. 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 22, 1978

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Wing web stab
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	April 9, 1984