



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1505.29
True Name	Equine Influenza Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Calvenza-03 EIV - No distributor specified
Date of Compilation Summary	February 01, 2024

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza virus
<b>Study Purpose</b>	Demonstration of efficacy against Equine influenza Kentucky Strain KY95
<b>Product Administration</b>	
<b>Study Animals</b>	Horses
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	July 13, 2000

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza virus
<b>Study Purpose</b>	Demonstration of efficacy against Equine influenza Ohio/03 strain
<b>Product Administration</b>	
<b>Study Animals</b>	Horses
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	This product class allows the manufacturer to update microorganisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
<b>USDA Approval Date</b>	January 22, 2008

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Equine influenza virus
<b>Study Purpose</b>	Demonstration of efficacy against Equine influenza NewMarket strain NM/2/93
<b>Product Administration</b>	
<b>Study Animals</b>	Horses
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	July 13, 2000

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions in horses including pregnant mares
<b>Product Administration</b>	
<b>Study Animals</b>	Horses
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	February 26, 2001