



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	16L1.00
True Name	Marek's Disease Vaccine, Serotype 1, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Cryomarex Rispens - Boehringer Ingelheim Animal Health do Brasil Ltda Rispens CVI 988 - Boehringer Ingelheim Animal Health Mexico Rispens CVI 988 - No distributor specified
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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's Disease
<b>Product Administration</b>	Subcutaneously
<b>Study Animals</b>	Chickens at 1 day of age
<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>	December 15, 1993

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	Subcutaneously
<b>Study Animals</b>	Chickens at 1 day of age
<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>	1994