



Summary of Studies Supporting USDA Product Licensure

| | |
|---|---|
| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 1631.00 |
| True Name | Marek's Disease Vaccine, Serotype 2, Live Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | SB1 - Boehringer Ingelheim Animal Health Mexico SB1 - No distributor specified |
| Date of Compilation Summary | August 11, 2020 |

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 | Marek's Disease Virus |
| Study Purpose | Efficacy against Marek's Disease |
| Product Administration | In ovo at 18-19 days of embryonation |
| Study Animals | Chickens |
| Challenge Description | Marek's Disease Virus RB1B |
| 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 15, 2002 |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Marek's Disease Virus |
| Study Purpose | Efficacy against Marek's Disease |
| Product Administration | Subcutaneous at day-of-age |
| Study Animals | Chickens |
| Challenge Description | Marek's Disease Virus RB1B |
| 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 26, 1990 |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Marek's Disease |
| Study Purpose | Efficacy against Marek's disease |
| Product Administration | Subcutaneously (SQ) |
| 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 | March 14, 1985 |

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | To evaluate safety under field conditions after subcutaneous administration to one-day-old chickens |
| 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 | April 9, 1985 |

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | Demonstrate in ovo safety under typical field conditions |
| Product Administration | |
| 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 23, 1994 |