# Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 1288.43 |
| True Name | Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Boehringer Ingelheim Animal Health Mexico |
| 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.**

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| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease virus, standard |
| **Study Purpose** | Demonstrate efficacy against standard infectious bursal disease virus |
| **Product Administration** | Subcutaneously |
| **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** | April 28, 1989 |

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| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease virus, standard |
| **Study Purpose** | Demonstrate efficacy against infectious bursal disease virus, standard |
| **Product Administration** | In ovo |
| **Study Animals** | Chicken eggs at 18 days of embryonation |
| **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 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease virus, standard |
| **Study Purpose** | Demonstrate efficacy against standard infectious bursal disease virus |
| **Product Administration** | Subcutaneously |
| **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 5, 1982 |

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|---|---|
| **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 |

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|---|---|
| **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** | October 8, 1993 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Marek's disease |
| **Study Purpose** | Demonstrate efficacy against Marek's disease |
| **Product Administration** | In ovo at 18 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** | May 23, 1994 |

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|---|---|
| **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 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Marek's Disease Virus |
| **Study Purpose** | Demonstrate efficacy against Marek's Disease |
| **Product Administration** | Subcutaneously |
| **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** | 1989 |

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|---|---|
| **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 |

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| **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 |

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|---|---|
| **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 |