



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 | 1288.45 |
| True Name | Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | |
| 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 | September 9, 1982 |

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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 | 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 | 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 | January 17, 1980 |

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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 |