



## 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  | 12C8.40  |
| True Name   | Bursal Disease-Marek's Disease Vaccine, Serotype 3, Standard & Variant, 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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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, standard   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against standard infectious bursal disease virus   |
| <b>Product Administration</b>            | Subcutaneously  |
| <b>Study Animals</b>                     | Chickens  |
| <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>                | September 9, 1982   |

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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, standard   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against infectious bursal disease virus, standard  |
| <b>Product Administration</b>            | In ovo  |
| <b>Study Animals</b>                     | Chicken eggs at 18 days of embryonation   |
| <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>                | May 23, 1994  |

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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, variant  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against infectious bursal disease virus, variant   |
| <b>Product Administration</b>            | In ovo  |
| <b>Study Animals</b>                     | Chicken eggs at 18 days of embryonation   |
| <b>Challenge Description</b>             | Variant 1084-E CP <sub>2</sub>  |
| <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>                | May 23, 1994  |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, standard   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against standard infectious bursal disease virus   |
| <b>Product Administration</b>            | Subcutaneously  |
| <b>Study Animals</b>                     | Chickens  |
| <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>                | May 5, 1982   |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, variant  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against infectious bursal disease virus, variant   |
| <b>Product Administration</b>            | Subcutaneous  |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             | Variant E   |
| <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>                | September 30, 1987  |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, variant  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against variant infectious bursal disease virus  |
| <b>Product Administration</b>            | In ovo  |
| <b>Study Animals</b>                     | Chickens  |
| <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 9, 1994  |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, standard   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against standard infectious bursal disease virus   |
| <b>Product Administration</b>            | In ovo  |
| <b>Study Animals</b>                     | Chickens  |
| <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 9, 1994  |



|  |   |
|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Marek's Disease Virus   |
| <b>Study Purpose</b>                     | Efficacy against Marek's Disease  |
| <b>Product Administration</b>            | In ovo at 18-19 days of embryonation  |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             | Marek's Disease Virus RB1B  |
| <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>                | October 8, 1993   |

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Marek's disease   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against Marek's disease  |
| <b>Product Administration</b>            | In ovo at 18 days of embryonation   |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             | Marek's Disease Virus RB1B  |
| <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>                | May 23, 1994  |

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

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|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Marek's disease virus   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against Marek's Disease  |
| <b>Product Administration</b>            | In ovo  |
| <b>Study Animals</b>                     | Chickens  |
| <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 9, 1994  |

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| <b>Study Type</b>                        | Safety  |
| <b>Pertaining to</b>                     | ALL   |
| <b>Study Purpose</b>                     | Demonstrate in ovo safety under typical field conditions  |
| <b>Product Administration</b>            |   |
| <b>Study Animals</b>                     | Chickens  |
| <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>                | May 23, 1994  |

|  |   |
|--|---|
| <b>Study Type</b>                        | Safety  |
| <b>Pertaining to</b>                     | ALL   |
| <b>Study Purpose</b>                     | Demonstrate safety under field conditions   |
| <b>Product Administration</b>            | Subcutaneously  |
| <b>Study Animals</b>                     | Chickens  |
| <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, 1987   |