# 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 | 12D5.01 |
| True Name | Bursal Disease-Reovirus Vaccine, Standard & Variant, Killed Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | |
| 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.**

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| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease, standard and variant E |
| **Study Purpose** | Demonstrate efficacy against infectious bursal disease, standard and variant E |
| **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** | October 4, 1995 |

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| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease, standard and variant E |
| **Study Purpose** | Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against infectious bursal disease, standard and variant E |
| **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** | August 1, 1991 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease, standard and variant E |
| **Study Purpose** | Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against infectious bursal disease, standard and variant E |
| **Product Administration** | Intramuscularly (IM) |
| **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** | August 27, 1992 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Infectious bursal disease, standard and variant E |
| **Study Purpose** | Demonstrate efficacy against bursal disease, standard and variant E |
| **Product Administration** | Intramuscularly (IM) |
| **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 21, 2005 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Avian reovirus |
| **Study Purpose** | Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against reovirus |
| **Product Administration** | Intramuscularly (IM) |
| **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 21, 2005 |

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Avian reovirus |
| **Study Purpose** | Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against reovirus |
| **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 22, 1993 |

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| **Study Type** | Safety |
| **Pertaining to** | ALL |
| **Study Purpose** | Demonstrate safety under field conditions |
| **Product Administration** | Intramuscularly (IM) |
| **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** | February 14, 2005 |

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|---|---|
| **Study Type** | Safety |
| **Pertaining to** | ALL |
| **Study Purpose** | Demonstrate safety under field conditions |
| **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** | June 28, 1995 |