

## Summary of Studies Supporting USDA Product Licensure

| Establishment Name  | Boehringer Ingelheim Animal Health USA Inc.           |
|---|---|
| USDA Vet Biologics<br>Establishment Number                                      | 124   |
| Product Code  | 1231.14   |
| True Name   | Bronchitis Vaccine, Mass & Conn Types, Live Virus     |
| Tradename(s) / Distributor or<br>Subsidiary<br>(if different from manufacturer) | Bron BLEN - Boehringer Ingelheim Animal Health Mexico |
| Date of Compilation<br>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.

|                               | 7.07  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Connecticut type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Connecticut type  |
| <b>Product Administration</b> | Drinking water  |
| Study Animals                 | Chickens  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. Study data, however, are no longer available. |
| USDA Approval Date            | March 28, 1977  |

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|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Massachusetts type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Massachusetts type  |
| <b>Product Administration</b> | Drinking water  |
| Study Animals                 | Chickens  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. No data are published because this study was submitted<br>to USDA-APHIS prior to January 1, 2007, and APHIS only requires<br>publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | March 28, 1977  |

|                               | 5.00  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Connecticut type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Connecticut type  |
| <b>Product Administration</b> |   |
| Study Animals                 | Chickens  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. No data are published because this study was submitted<br>to USDA-APHIS prior to January 1, 2007, and APHIS only requires<br>publication of data submitted after that date. |
| USDA Approval Date            | October 28, 1976  |

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Avian infectious bronchitis virus, Connecticut type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Connecticut type  |
| <b>Product Administration</b> |   |
| Study Animals                 | Chickens  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. No data are published because this study was submitted<br>to USDA-APHIS prior to January 1, 2007, and APHIS only requires<br>publication of data submitted after that date. |
| USDA Approval Date            | July 1, 1976  |

|                               | 5.00  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Connecticut type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Connecticut type  |
| <b>Product Administration</b> |   |
| Study Animals                 | Chicken   |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. No data are published because this study was submitted<br>to USDA-APHIS prior to January 1, 2007, and APHIS only requires<br>publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | August 13, 1979   |

|                               | 7.07  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Massachusetts type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Massachusetts type  |
| <b>Product Administration</b> |   |
| Study Animals                 | Chicken   |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. Study data, however, are no longer available. |
| <b>USDA Approval Date</b>     | August 13, 1979   |

|                               | 7.07  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Massachusetts type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Massachusetts type  |
| <b>Product Administration</b> | Drinking water  |
| Study Animals                 | Chickens  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. Study data, however, are no longer available. |
| USDA Approval Date            | September 24, 1976  |

|                               | 7.00  |
|-------------------------------|---|
| Study Type                    | Efficacy  |
| Pertaining to                 | Avian infectious bronchitis virus, Massachusetts type   |
| Study Purpose                 | Demonstrate efficacy against avian infectious bronchitis virus,   |
|                               | Massachusetts type  |
| <b>Product Administration</b> |   |
| Study Animals                 | Chickens  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. Study data, however, are no longer available. |
| USDA Approval Date            | July 2, 1976  |

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|-------------------------|---|
| Study Type              | Safety  |
| Pertaining to           | ALL   |
| Study Purpose           | To evaluate safety under field conditions   |
| Product Administration  | Drinking water  |
| Study Animals           | Chickens  |
| Challenge Description   |   |
| Interval observed after |   |
| challenge               |   |
| Results                 | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time of<br>submission. Study data, however, are no longer available. |
| USDA Approval Date      | April 9, 1984   |