



## Summary of Studies Supporting USDA Product Licensure

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| Establishment Name  | Intervet Inc.  |
| USDA Vet Biologics Establishment Number                                   | 165A   |
| Product Code  | 16J1.R2  |
| True Name   | Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotypes 2 & 3, Modified Live & Live Marek's Disease Vector |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Merck Animal Health  |
| Date of Compilation Summary   | October 28, 2021   |

**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 Laryngotracheitis Virus  |
| <b>Study Purpose</b>                     | To demonstrate efficacy against infectious laryngotracheitis virus 10 weeks after vaccination   |
| <b>Product Administration</b>            | One dose administered <i>in ovo</i> at 18 days of embryonation.   |
| <b>Study Animals</b>                     | Specific-pathogen-free chickens divided into groups:<br>Vaccinates: 30 chickens<br>Positive Controls (10 weeks old at challenge): 10 chickens<br>Positive Controls (4 weeks old at challenge): 10 chickens  |
| <b>Challenge Description</b>             | Challenged with ILT virus 10 weeks post-vaccination.  |
| <b>Interval observed after challenge</b> | Observed for clinical signs for 10 days post-challenge.   |
| <b>Results</b>                           | <p>Summary of results:</p> <p>Birds positive for Infectious Laryngotracheitis Disease (see raw data table below for positivity criteria):</p> <p>Vaccinates: 1/30 (3%)<br/> 10-week-old Controls: 7/9* (78%)<br/> 4-week-Old Controls: 10/10 (100%)</p> <p>*One chicken died two days following challenge and the death was determined not related to the challenge.</p> <p>Requirements per 9 CFR 113.328 were met. The 4-week-old controls group validated the virulence of challenge.</p> <p>Raw data attached</p> |
| <b>USDA Approval Date</b>                | December 14, 2007   |

## Individual Bird Challenge Data

| Bird ID | Treatment Group | Date:   |         |         |         |         |         |         |         |         |         | Clinical Result<br>(+ or -) | Necropsy Result<br>(+ or -) |   |
|---------|-----------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|-----------------------------|-----------------------------|---|
|         |                 | 8/17/07 | 8/18/07 | 8/19/07 | 8/20/07 | 8/21/07 | 8/22/07 | 8/23/07 | 8/24/07 | 8/25/06 | 8/26/07 |                             |                             |   |
| 2558    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2560    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2561    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2569    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2572    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2582    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2588    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2594    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2599    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2553    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2563    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2568    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2586    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2590    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2592    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2595    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2552    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2555    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2566    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2574    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2575    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2587    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2597    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2601    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2559    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2562    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2571    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2576    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2580    | Vaccinate       |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2589    | Vaccinate       |         |         |         | G       | D       |         |         |         |         |         |                             | +                           | + |
| 2668*   | Placebo         |         | D       |         |         |         |         |         |         |         |         |                             |                             | - |
| 2661    | Placebo         |         |         |         |         | G       | GA      |         |         |         |         |                             | +                           |   |
| 2674    | Placebo         |         |         | G       | G       | D       |         |         |         |         |         |                             | +                           | + |
| 2676    | Placebo         |         |         |         |         | D       |         |         |         |         |         |                             |                             | + |
| 2666    | Placebo         |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2667    | Placebo         |         |         | G       | G       | AG      | AG      | D       |         |         |         |                             | +                           | + |
| 2673    | Placebo         |         |         |         |         |         |         |         |         |         |         |                             | -                           |   |
| 2663    | Placebo         |         |         | G       | G       | G       |         |         |         |         |         |                             | +                           |   |
| 2672    | Placebo         |         |         |         | G       | G       |         |         |         |         |         |                             | +                           |   |
| 2682    | Placebo         |         |         | G       | G       | G       |         |         |         |         |         |                             | +                           |   |
| 4260    | Control         |         |         | GA      | GA      | A       |         |         |         |         |         |                             | +                           |   |
| 4264    | Control         |         |         | A       | GA      | AG      | A       |         |         |         |         |                             | +                           | + |
| 4265    | Control         |         |         | A       | A       | D       |         |         |         |         |         |                             | +                           |   |
| 4266    | Control         |         |         | GA      | GA      | GAO     |         |         |         |         |         |                             | +                           |   |
| 4269    | Control         |         |         | GA      | GA      | A       |         |         |         |         |         |                             | +                           |   |
| 4270    | Control         |         |         | GA      | GA      | A       |         |         |         |         |         |                             | +                           |   |
| 4271    | Control         |         |         | G       | G/D     |         |         |         |         |         |         |                             | +                           | + |
| 4272    | Control         |         |         | A       | A       | GA      | D       |         |         |         |         |                             | +                           | + |
| 4276    | Control         |         |         | GA      | GA      | OAG     |         |         |         |         |         |                             | +                           |   |
| 4284    | Control         |         |         | A       | GA      | GA      |         |         |         |         |         |                             | +                           |   |

**Clinical Signs:** (D) Dead; (G) Gasping; (L) Acute Labored Breathing; (B) Expectoration of Blood; (O) Acute Ocular Discharge/Swelling and/or Sinus Swelling; (A) General Appearance, Huddled with Ruffled Feathers, Depression, and/or emaciation

**NOTE:** If general appearance is only clinical sign, bird is considered positive if it remains morbid throughout remainder of observation and morbidity cannot be attributed to other causes.

**Clinical Findings:** Birds exhibiting a clinical sign for 2 or more days are considered positive (+)

\* Bird 2668 was not included in the final challenge results as mortality was not related to challenge.

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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Marek's Disease Virus (MDV), Infectious Laryngotracheitis Virus (ILT)   |
| <b>Study Purpose</b>                     | To demonstrate effectiveness against very virulent MDV and ILT.   |
| <b>Product Administration</b>            | <i>In ovo</i>   |
| <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>                | August 29, 2006   |

| <b>Study Type</b>                        | Safety   |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
|--|--|--------------|----------------|--------------|--------------------|-------------|--------------------|---|-----------|---------|-----------|-----------|-----------|---------|---------|-----------|-----------|-----------|---|-----------|---------|-----------|------------|------------|-----------|----|-----------|----|----|---|-----------|-----------|-----------|-----------|-----------|---------|-----------|-----------|-----------|-----------|
| <b>Pertaining to</b>                     | ALL  |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Study Purpose</b>                     | To demonstrate safety of product under typical field conditions  |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Product Administration</b>            | One dose was administered <i>in ovo</i> to 18-19 day old chicken embryos.  |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Study Animals</b>                     | A total of 2,366,613 chickens, representing 3 distinct geographical locations.   |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Challenge Description</b>             | N/A  |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Interval observed after challenge</b> | Chicks were observed daily for mortality through 14 days post-hatch.   |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>Results</b>                           | <table border="1"> <thead> <tr> <th>Site</th> <th>Group</th> <th>Total Placed</th> <th>% Hatchability</th> <th>% Mortality</th> <th>Condemnation Rates</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>681,138</td> <td>69.1-92.1</td> <td>0.99-3.57</td> <td>0.36-1.37</td> </tr> <tr> <td>Control</td> <td>702,801</td> <td>65.5-92.1</td> <td>0.93-2.36</td> <td>0.65-1.15</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>343,155</td> <td>73.0-93.4</td> <td>2.61-5.38*</td> <td>0.37-0.47*</td> </tr> <tr> <td>Control**</td> <td>--</td> <td>73.7-87.5</td> <td>--</td> <td>--</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>1,342,320</td> <td>72.9-91.3</td> <td>4.50-5.17</td> <td>0.78-1.12</td> </tr> <tr> <td>Control</td> <td>1,436,083</td> <td>70.3-91.2</td> <td>0.79-1.58</td> <td>0.79-1.58</td> </tr> </tbody> </table> <p>*8 total houses that had test vaccinated birds, however only 2 has all test birds. Percent mortality and condemnation rates were determined based on the 2 houses with test birds only.</p> <p>** Percent hatchability for Site 2 controls was the "Standard Hatch" value provided by the site.</p> <p>No adverse reactions attributable to vaccination with the test article were reported.</p> | Site         | Group          | Total Placed | % Hatchability     | % Mortality | Condemnation Rates | 1 | Vaccinate | 681,138 | 69.1-92.1 | 0.99-3.57 | 0.36-1.37 | Control | 702,801 | 65.5-92.1 | 0.93-2.36 | 0.65-1.15 | 2 | Vaccinate | 343,155 | 73.0-93.4 | 2.61-5.38* | 0.37-0.47* | Control** | -- | 73.7-87.5 | -- | -- | 3 | Vaccinate | 1,342,320 | 72.9-91.3 | 4.50-5.17 | 0.78-1.12 | Control | 1,436,083 | 70.3-91.2 | 0.79-1.58 | 0.79-1.58 |
| Site                                     | Group  | Total Placed | % Hatchability | % Mortality  | Condemnation Rates |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| 1  | Vaccinate  | 681,138      | 69.1-92.1      | 0.99-3.57    | 0.36-1.37          |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
|  | Control  | 702,801      | 65.5-92.1      | 0.93-2.36    | 0.65-1.15          |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| 2  | Vaccinate  | 343,155      | 73.0-93.4      | 2.61-5.38*   | 0.37-0.47*         |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
|  | Control**  | --           | 73.7-87.5      | --           | --                 |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| 3  | Vaccinate  | 1,342,320    | 72.9-91.3      | 4.50-5.17    | 0.78-1.12          |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
|  | Control  | 1,436,083    | 70.3-91.2      | 0.79-1.58    | 0.79-1.58          |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |
| <b>USDA Approval Date</b>                | April 13, 2009   |              |                |              |                    |             |                    |   |           |         |           |           |           |         |         |           |           |           |   |           |         |           |            |            |           |    |           |    |    |   |           |           |           |           |           |         |           |           |           |           |