



## Summary of Studies Supporting USDA Product Licensure

|   |  |
|---|--|
| Establishment Name  | Merial, Inc.   |
| USDA Vet Biologics Establishment Number                                   | 298  |
| Product Code  | 1281.R3  |
| True Name   | Bursal Disease-Marek's Disease Vaccine, Serotypes 1 & 3, Live Marek's Disease Vector, Live Herpesvirus Chimera |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Prevexxion RN & Vaxxitek HVT + IBD - No distributor specified  |
| Date of Compilation Summary   | July 16, 2018  |

**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.**

| <b>Study Type</b>                        | Efficacy   |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
|--|--|--------|-------|------|------|------|----|-----|--------|-----------|------|------|------|------|------|---------|------|------|------|------|------|------|-----------|------|------|------|------|------|---------|------|------|------|------|------|
| <b>Pertaining to</b>                     | Bursal disease virus variant E   |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Study Purpose</b>                     | Demonstrate efficacy against variant bursal disease  |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Product Administration</b>            | One dose administered <i>in ovo</i>  |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Study Animals</b>                     | 3 groups of 20 SPF eggs each<br><br>Group 2 vaccinated and challenged<br>Group 4 sham vaccinated and challenged (challenge control/placebo)<br>Group 5 sham vaccinated and sham challenged (negative control)  |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Challenge Description</b>             | IBDV variant E challenge administered at 28 days of age (Study Day 31)   |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Interval observed after challenge</b> | Observed daily for 11 post-challenge and target tissues examined for gross bursal lesions  |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>Results</b>                           | <p>The body weight and bursal weight were collected and B/B wt. ratio (bursa weight/body weight ratio) was calculated for each bird and compared between vaccinates and challenge controls/placebos.</p> <table border="1"> <thead> <tr> <th>Gender</th> <th>Group</th> <th>Min</th> <th>Q1</th> <th>Med</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Female</td> <td>Vaccinate</td> <td>0.16</td> <td>0.33</td> <td>0.48</td> <td>0.64</td> <td>0.79</td> </tr> <tr> <td>Placebo</td> <td>0.05</td> <td>0.10</td> <td>0.11</td> <td>0.13</td> <td>0.16</td> </tr> <tr> <td rowspan="2">Male</td> <td>Vaccinate</td> <td>0.06</td> <td>0.35</td> <td>0.44</td> <td>0.45</td> <td>0.54</td> </tr> <tr> <td>Placebo</td> <td>0.07</td> <td>0.10</td> <td>0.12</td> <td>0.13</td> <td>0.20</td> </tr> </tbody> </table> <p>Min is minimum<br/>Q is quartile<br/>Med is Median<br/>Max is maximum</p> <p>Raw data attached.</p> | Gender | Group | Min  | Q1   | Med  | Q3 | Max | Female | Vaccinate | 0.16 | 0.33 | 0.48 | 0.64 | 0.79 | Placebo | 0.05 | 0.10 | 0.11 | 0.13 | 0.16 | Male | Vaccinate | 0.06 | 0.35 | 0.44 | 0.45 | 0.54 | Placebo | 0.07 | 0.10 | 0.12 | 0.13 | 0.20 |
| Gender                                   | Group  | Min    | Q1    | Med  | Q3   | Max  |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| Female                                   | Vaccinate  | 0.16   | 0.33  | 0.48 | 0.64 | 0.79 |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
|  | Placebo  | 0.05   | 0.10  | 0.11 | 0.13 | 0.16 |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| Male                                     | Vaccinate  | 0.06   | 0.35  | 0.44 | 0.45 | 0.54 |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
|  | Placebo  | 0.07   | 0.10  | 0.12 | 0.13 | 0.20 |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |
| <b>USDA Approval Date</b>                | November 14, 2017  |        |       |      |      |      |    |     |        |           |      |      |      |      |      |         |      |      |      |      |      |      |           |      |      |      |      |      |         |      |      |      |      |      |

|       |   |                     |     | Bursa Weight (g) | Body Weight (g) | B/BW Ratio |
|-------|---|---------------------|-----|------------------|-----------------|------------|
| Group | Vaccine   | Challenge           | ID  |                  |                 |            |
| 2     | Test vaccine                                    | IBDV VAR-E (Day 31) | 260 | 0.68             | 416.00          | 0.16       |
|       |   |                     | 273 | 2.25             | 509.00          | 0.44       |
|       |   |                     | 276 | 2.34             | 488.00          | 0.48       |
|       |   |                     | 279 | 1.03             | 458.00          | 0.22       |
|       |   |                     | 285 | 3.13             | 497.00          | 0.63       |
|       |   |                     | 287 | 2.30             | 527.00          | 0.44       |
|       |   |                     | 296 | 1.79             | 518.00          | 0.35       |
|       |   |                     | 303 | 2.58             | 531.00          | 0.49       |
|       |   |                     | 309 | 2.50             | 386.00          | 0.65       |
|       |   |                     | 319 | 2.34             | 537.00          | 0.44       |
|       |   |                     | 320 | 2.00             | 468.00          | 0.43       |
|       |   |                     | 325 | 4.06             | 516.00          | 0.79       |
|       |   |                     | 326 | 0.30             | 531.00          | 0.08       |
|       |   |                     | 334 | 2.34             | 529.00          | 0.44       |
|       |   |                     | 335 | 2.96             | 460.00          | 0.64       |
|       |   |                     | 336 | 1.53             | 459.00          | 0.33       |
|       |   |                     | 342 | 3.22             | 596.00          | 0.54       |
|       |   |                     | 343 | 2.81             | 564.00          | 0.50       |
|       |   |                     | 348 | 2.46             | 551.00          | 0.45       |
|       |   |                     | 355 | 0.71             | 542.00          | 0.13       |
| 4     | Sham-vaccinated / IBDV VAR-E Challenge Controls | IBDV VAR-E (Day 31) | 266 | 0.38             | 398.00          | 0.10       |
|       |   |                     | 272 | 0.51             | 423.00          | 0.12       |
|       |   |                     | 274 | 0.56             | 362.00          | 0.15       |
|       |   |                     | 275 | 1.04             | 520.00          | 0.20       |
|       |   |                     | 280 | 0.36             | 517.00          | 0.07       |
|       |   |                     | 292 | 0.52             | 428.00          | 0.12       |
|       |   |                     | 293 | 0.48             | 428.00          | 0.11       |
|       |   |                     | 294 | 0.87             | 623.00          | 0.14       |
|       |   |                     | 298 | 0.58             | 474.00          | 0.12       |
|       |   |                     | 304 | 0.58             | 426.00          | 0.14       |
|       |   |                     | 305 | 0.29             | 430.00          | 0.07       |
|       |   |                     | 311 | 0.45             | 405.00          | 0.11       |
|       |   |                     | 315 | 0.70             | 530.00          | 0.13       |
|       |   |                     | 316 | 0.75             | 458.00          | 0.16       |
|       |   |                     | 331 | 0.47             | 476.00          | 0.10       |
|       |   |                     | 344 | 0.54             | 454.00          | 0.12       |
|       |   |                     | 347 | 0.40             | 543.00          | 0.07       |
|       |   |                     | 349 | 0.42             | 394.00          | 0.11       |
|       |   |                     | 352 | 0.22             | 415.00          | 0.05       |
|       |   |                     | 354 | 0.48             | 421.00          | 0.11       |

Day 31 denotes day of study and day of challenge

|     |  |                         | Bursa Weight (g) | Body Weight (g) | B/BW Ratio |      |
|-----|--|-------------------------|------------------|-----------------|------------|------|
| 5   | Sham-vaccinated, sham-challenged (Negative Controls) | Sham Challenge (Day 31) | 259              | 1.09            | 493.00     | 0.22 |
|     |  |                         | 262              | 4.31            | 622.00     | 0.69 |
|     |  |                         | 264              | 2.41            | 569.00     | 0.42 |
|     |  |                         | 267              | 3.73            | 444.00     | 0.84 |
|     |  |                         | 269              | 3.74            | 444.00     | 0.84 |
|     |  |                         | 270              | 2.41            | 548.00     | 0.44 |
|     |  |                         | 271              | 2.42            | 519.00     | 0.47 |
|     |  |                         | 282              | 2.97            | 560.00     | 0.53 |
|     |  |                         | 283              | 2.69            | 492.00     | 0.55 |
|     |  |                         | 295              | 1.78            | 475.00     | 0.37 |
|     |  |                         | 308              | 2.22            | 670.00     | 0.33 |
|     |  |                         | 312              | 2.36            | 470.00     | 0.50 |
|     |  |                         | 322              | 2.63            | 594.00     | 0.44 |
|     |  |                         | 324              | 2.04            | 514.00     | 0.40 |
|     |  |                         | 328              | 2.65            | 520.00     | 0.51 |
|     |  |                         | 332              | 1.93            | 445.00     | 0.43 |
|     |  |                         | 339              | 3.56            | 568.00     | 0.63 |
|     |  |                         | 345              | 2.00            | 503.00     | 0.40 |
| 350 | 2.81   | 471.00                  | 0.60             |                 |            |      |
| 356 | 3.56   | 479.00                  | 0.74             |                 |            |      |

Day 31 denotes day of study and day of challenge

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| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Bursal disease virus standard  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against bursal disease standard strain  |
| <b>Product Administration</b>            | One dose administered in ovo route   |
| <b>Study Animals</b>                     | SPF eggs divided into 2 groups<br><br>Group 1 vaccinated and challenged<br>Group 2 sham vaccinated and challenged (positive control)   |
| <b>Challenge Description</b>             | IBDV standard challenge administered at 28 days of age   |
| <b>Interval observed after challenge</b> | Observed daily for 4 days and necropsied to examine for gross bursal lesions   |
| <b>Results</b>                           | Vaccinates and controls were evaluated in terms of bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c).<br><br>Birds with gross observable lesions:<br>Group 1: 2/40<br>Group 2: 38/40<br><br>Requirements of 9 CFR 113.331(c) were met.<br><br>Raw data on attached page |
| <b>USDA Approval Date</b>                | October 19, 2017   |

| Group/Bird | Peri-Bursal Edema | Edema | Macroscopic Hemorrhage | Bursal Disease Score | Comments   |
|------------|-------------------|-------|------------------------|----------------------|------------|
| 1/1        |                   | X     |                        | Positive             |            |
| 1/2        |                   | X     |                        | Positive             |            |
| 2/1        |                   | X     |                        | Positive             |            |
| 2/2        |                   | X     |                        | Positive             |            |
| 2/3        |                   | X     |                        | Positive             |            |
| 2/4        |                   | X     |                        | Positive             |            |
| 2/5        |                   | X     |                        | Positive             |            |
| 2/6        | X                 |       |                        | Positive             |            |
| 2/7        |                   | X     |                        | Positive             |            |
| 2/8        |                   | X     |                        | Positive             |            |
| 2/9        |                   | X     |                        | Positive             |            |
| 2/10       |                   | X     |                        | Positive             |            |
| 2/11       | X                 |       | X                      | Positive             | Found Dead |
| 2/12       |                   | X     |                        | Positive             |            |
| 2/13       |                   | X     |                        | Positive             |            |
| 2/14       |                   | X     |                        | Positive             |            |
| 2/15       |                   | X     |                        | Positive             |            |
| 2/16       |                   | X     |                        | Positive             |            |
| 2/17       |                   | X     |                        | Positive             |            |
| 2/18       |                   | X     |                        | Positive             |            |
| 2/19       |                   | X     |                        | Positive             |            |
| 2/20       |                   | X     |                        | Positive             |            |
| 2/21       |                   | X     |                        | Positive             |            |
| 2/22       |                   | X     |                        | Positive             |            |
| 2/23       |                   | X     |                        | Positive             |            |
| 2/24       |                   | X     |                        | Positive             |            |
| 2/25       |                   | X     |                        | Positive             |            |
| 2/26       |                   | X     |                        | Positive             |            |
| 2/27       |                   | X     |                        | Positive             |            |
| 2/28       |                   | X     |                        | Positive             |            |
| 2/29       |                   | X     |                        | Positive             |            |
| 2/30       |                   | X     |                        | Positive             |            |
| 2/31       |                   | X     |                        | Positive             |            |
| 2/32       |                   | X     |                        | Positive             |            |
| 2/33       |                   | X     |                        | Positive             |            |
| 2/34       |                   | X     |                        | Positive             |            |
| 2/35       |                   | X     |                        | Positive             | Found Dead |
| 2/36       |                   | X     |                        | Positive             |            |
| 2/37       |                   | X     |                        | Positive             |            |
| 2/38       |                   | X     |                        | Positive             |            |

|  |  |
|--|--|
| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Infectious bursal disease virus, standard  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against infectious bursal disease, standard   |
| <b>Product Administration</b>            | One dose subcutaneously (SQ) at day of age   |
| <b>Study Animals</b>                     | One-day-old SPF chicks, 20 per group<br><br>Group 1: Vaccinated, challenged<br>Group 7: Placebo vaccinated, challenged (Control)   |
| <b>Challenge Description</b>             | IBDV Classical STC challenge, 28 days after vaccination  |
| <b>Interval observed after challenge</b> | Observed for 4 days post-challenge then examined for gross bursal lesions at necropsy  |
| <b>Results</b>                           | Animals were evaluated for signs of gross bursal lesions per the criteria in 9 CFR 113.331(b)(2)(i).<br><br>Birds with observable lesions:<br>Group 1: 0/20<br>Group 7: 20/20<br><br>Requirements of 9 CFR 113.331(c)(3)(ii) were met.<br><br>Raw data of affected chickens on attached page |
| <b>USDA Approval Date</b>                | January 28, 2014   |

| <b>Group</b> | <b>Bird ID</b> | <b>Bursal Disease Score</b> |
|--------------|----------------|-----------------------------|
| 7            | 257            | Positive                    |
| 7            | 258            | Positive                    |
| 7            | 262            | Positive                    |
| 7            | 256            | Positive                    |
| 7            | 255            | Positive                    |
| 7            | 261            | Positive                    |
| 7            | 251            | Positive                    |
| 7            | 259            | Positive                    |
| 7            | 254            | Positive                    |
| 7            | 260            | Positive                    |
| 7            | 263            | Positive                    |
| 7            | 264            | Positive                    |
| 7            | 265            | Positive                    |
| 7            | 266            | Positive                    |
| 7            | 268            | Positive                    |
| 7            | 270            | Positive                    |
| 7            | 271            | Positive                    |
| 7            | 272            | Positive                    |
| 7            | 273            | Positive                    |
| 7            | 275            | Positive                    |



| <b>Study Type</b>                        | Efficacy  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
|--|---|-------|--------|------|--------|----|------|---|------|------|------|------|------|---|------|------|------|------|------|---|------|------|------|------|------|---|------|------|------|------|------|
| <b>Pertaining to</b>                     | Infectious bursal disease virus, variant E  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Study Purpose</b>                     | Demonstrate efficacy against variant infectious bursal disease variant E  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Product Administration</b>            | One dose subcutaneously (SQ) at day of age  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Study Animals</b>                     | One-day-old SPF chicks, 20 per group<br><br>Group 2: Vaccinated, challenged<br>Group 3: Vaccinated, sham challenged<br>Group 8: Placebo vaccinated, challenged<br>Group 9: Placebo vaccinated, sham challenged  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Challenge Description</b>             | IBDV Variant (VAR-E) challenge, 28 days after vaccination   |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Interval observed after challenge</b> | Body and bursal weights collected 11 days post-challenge. Sex of birds was recorded.  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>Results</b>                           | <p>Bursal ratios (bursa weight/body weight ratio X 100) were calculated for each animal</p> <p>5-number summary for the bursal to body weight ratio per treatment group.</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Min.</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Max.</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>0.31</td> <td>0.44</td> <td>0.49</td> <td>0.53</td> <td>0.84</td> </tr> <tr> <td>3</td> <td>0.31</td> <td>0.44</td> <td>0.49</td> <td>0.57</td> <td>0.69</td> </tr> <tr> <td>8</td> <td>0.08</td> <td>0.10</td> <td>0.12</td> <td>0.13</td> <td>0.16</td> </tr> <tr> <td>9</td> <td>0.33</td> <td>0.46</td> <td>0.49</td> <td>0.56</td> <td>0.87</td> </tr> </tbody> </table> <p>Min. is minimum<br/>Q is quartile<br/>Max. is maximum</p> <p>Raw data on attached page.</p> | Group | Min.   | Q1   | Median | Q3 | Max. | 2 | 0.31 | 0.44 | 0.49 | 0.53 | 0.84 | 3 | 0.31 | 0.44 | 0.49 | 0.57 | 0.69 | 8 | 0.08 | 0.10 | 0.12 | 0.13 | 0.16 | 9 | 0.33 | 0.46 | 0.49 | 0.56 | 0.87 |
| Group                                    | Min.  | Q1    | Median | Q3   | Max.   |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| 2  | 0.31  | 0.44  | 0.49   | 0.53 | 0.84   |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| 3  | 0.31  | 0.44  | 0.49   | 0.57 | 0.69   |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| 8  | 0.08  | 0.10  | 0.12   | 0.13 | 0.16   |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| 9  | 0.33  | 0.46  | 0.49   | 0.56 | 0.87   |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |
| <b>USDA Approval Date</b>                | January 28, 2014  |       |        |      |        |    |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |   |      |      |      |      |      |

**Raw data shown below**

| <b>Group</b> | <b>ID No.</b> | <b>Sex<br/>(M=male,<br/>F=female)</b> | <b>Body<br/>weight<br/>(g)</b> | <b>Bursa<br/>weight<br/>(g)</b> |
|--------------|---------------|---------------------------------------|--------------------------------|---------------------------------|
| 2            | 235           | M                                     | 469                            | 2.26                            |
| 2            | 236           | M                                     | 416                            | 2.34                            |
| 2            | 232           | F                                     | 385                            | 1.7                             |
| 2            | 234           | F                                     | 356                            | 1.82                            |
| 2            | 233           | F                                     | 502                            | 4.21                            |
| 2            | 229           | F                                     | 468                            | 2.46                            |
| 2            | 230           | M                                     | 480                            | 2.53                            |
| 2            | 237           | M                                     | 461                            | 1.44                            |
| 2            | 228           | F                                     | 462                            | 2.07                            |
| 2            | 226           | M                                     | 436                            | 2.2                             |
| 2            | 240           | M                                     | 555                            | 3.09                            |
| 2            | 247           | F                                     | 514                            | 2.33                            |
| 2            | 244           | F                                     | 463                            | 1.87                            |
| 2            | 243           | F                                     | 449                            | 2.2                             |
| 2            | 238           | F                                     | 451                            | 1.78                            |
| 2            | 249           | F                                     | 441                            | 2.68                            |
| 2            | 250           | M                                     | 526                            | 2.54                            |
| 2            | 248           | M                                     | 497                            | 1.78                            |
| 2            | 246           | M                                     | 471                            | 2.4                             |
| 2            | 241           | M                                     | 407                            | 1.84                            |
| 3            | 162           | M                                     | 523                            | 3.6                             |
| 3            | 157           | M                                     | 576                            | 2.67                            |
| 3            | 158           | F                                     | 420                            | 1.94                            |
| 3            | 152           | M                                     | 483                            | 2.84                            |
| 3            | 153           | M                                     | 487                            | 2.64                            |
| 3            | 151           | M                                     | 496                            | 2.88                            |
| 3            | 154           | F                                     | 377                            | 1.17                            |
| 3            | 155           | F                                     | 425                            | 1.32                            |
| 3            | 161           | F                                     | 393                            | 1.85                            |
| 3            | 156           | M                                     | 483                            | 2.35                            |
| 3            | 169           | M                                     | 477                            | 2.46                            |
| 3            | 164           | F                                     | 381                            | 2.15                            |
| 3            | 175           | F                                     | 419                            | 2.23                            |
| 3            | 167           | F                                     | 393                            | 2.34                            |
| 3            | 170           | M                                     | 472                            | 2.85                            |
| 3            | 163           | F                                     | 461                            | 1.94                            |
| 3            | 172           | M                                     | 505                            | 2.15                            |
| 3            | 174           | M                                     | 557                            | 2.62                            |
| 3            | 165           | F                                     | 427                            | 2.07                            |

|   |     |   |     |      |
|---|-----|---|-----|------|
| 3 | 173 | M | 511 | 1.76 |
| 8 | 307 | M | 470 | 0.59 |
| 8 | 303 | M | 614 | 0.87 |
| 8 | 310 | F | 445 | 0.54 |
| 8 | 306 | F | 441 | 0.54 |
| 8 | 311 | F | 433 | 0.43 |
| 8 | 305 | F | 473 | 0.41 |
| 8 | 308 | F | 386 | 0.63 |
| 8 | 302 | M | 472 | 0.61 |
| 8 | 304 | F | 410 | 0.55 |
| 8 | 301 | M | 508 | 0.67 |
| 8 | 322 | M | 505 | 0.62 |
| 8 | 323 | M | 546 | 0.65 |
| 8 | 317 | F | 443 | 0.68 |
| 8 | 316 | M | 528 | 0.63 |
| 8 | 319 | M | 500 | 0.72 |
| 8 | 314 | F | 479 | 0.47 |
| 8 | 320 | F | 482 | 0.44 |
| 8 | 313 | F | 468 | 0.39 |
| 8 | 315 | F | 476 | 0.37 |
| 8 | 321 | F | 438 | 0.47 |
| 9 | 206 | M | 570 | 2.77 |
| 9 | 204 | M | 435 | 2.14 |
| 9 | 201 | M | 550 | 2.52 |
| 9 | 207 | F | 497 | 2.53 |
| 9 | 209 | M | 498 | 2.27 |
| 9 | 211 | M | 515 | 3.07 |
| 9 | 208 | F | 512 | 3.5  |
| 9 | 212 | F | 429 | 3.75 |
| 9 | 203 | M | 522 | 2.96 |
| 9 | 202 | F | 458 | 1.52 |
| 9 | 215 | F | 503 | 3.13 |
| 9 | 221 | M | 535 | 2.72 |
| 9 | 220 | M | 504 | 2.41 |
| 9 | 219 | M | 491 | 2.02 |
| 9 | 222 | M | 525 | 2.89 |
| 9 | 225 | F | 410 | 2.05 |
| 9 | 216 | F | 409 | 1.87 |
| 9 | 223 | M | 521 | 2.56 |
| 9 | 217 | F | 433 | 1.76 |
| 9 | 224 | F | 444 | 2.24 |

|  |  |
|--|--|
| <b>Study Type</b>                        | Efficacy   |
| <b>Pertaining to</b>                     | Marek's Disease Virus, serotype 1  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against very virulent Marek's disease   |
| <b>Product Administration</b>            | One dose administered <i>in ovo</i>  |
| <b>Study Animals</b>                     | SPF eggs divided into 4 groups<br><br>Group 1 vaccinated with test product and challenged<br>Group 2 sham vaccinated and challenged (control)<br>Group 3 sham vaccinated and not challenged (control)<br>Group 4 vaccinated with a serotype 3 Marek's vaccine and challenged (control)   |
| <b>Challenge Description</b>             | Serotype-1 (SR-1) RB1B strain administered at 5 days of age  |
| <b>Interval observed after challenge</b> | Observed daily for 50 days and then evaluated for internal lesions   |
| <b>Results</b>                           | Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5).<br><br>Birds with clinical signs and/or observable lesions:<br>Group 1: 6/33<br>Group 2: 35/35<br>Group 3: 0/35<br>Group 4: 11/35<br><br>Requirements of 9 CFR 113.330(c)(4) & (5) were met.<br><br>Raw data on attached page |
| <b>USDA Approval Date</b>                | November 30, 2016  |

Raw data shown below for birds classified as positive. All other birds normal.

| Group/Bird | Paralysis | Locomotive_Signs | Emaciation | Depression | Other Clinical Signs | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|------------|-----------|------------------|------------|------------|----------------------|-------|--------|-------|--------|--------|---------|---------------------|----------|
| 1/1        |           |                  |            |            |                      | X     | X      |       |        |        | X       |                     |          |
| 1/2        |           |                  |            | X          |                      |       |        |       |        | X      | X       |                     |          |
| 1/3        |           |                  |            |            |                      | X     | X      |       |        | X      | X       |                     |          |
| 1/4        |           |                  |            |            |                      | X     | X      |       |        | X      | X       |                     |          |
| 1/5        |           |                  |            |            |                      |       | X      |       |        | X      | X       |                     |          |
| 1/6        |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/1        |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/2        |           | X                |            |            |                      | X     |        |       |        |        | X       |                     |          |
| 2/3        |           | X                |            | X          |                      |       |        |       |        |        | X       |                     |          |
| 2/4        |           | X                |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/5        |           |                  |            | X          |                      |       |        |       |        |        | X       |                     |          |
| 2/6        |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |
| 2/7        |           |                  |            | X          |                      |       | X      |       |        | X      | X       |                     |          |
| 2/8        |           |                  |            | X          |                      | X     |        |       |        |        | X       |                     |          |
| 2/9        |           |                  |            | X          |                      | X     |        | X     |        |        | X       |                     |          |
| 2/10       |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |
| 2/11       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/12       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/13       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/14       |           |                  |            | X          |                      |       | X      |       |        | X      |         |                     |          |
| 2/15       |           |                  |            | X          |                      |       |        |       |        |        | X       |                     |          |
| 2/16       |           |                  |            | X          |                      |       | X      |       |        | X      | X       |                     |          |
| 2/17       |           |                  |            | X          |                      |       |        |       |        |        |         |                     |          |
| 2/18       |           |                  |            | X          |                      |       | X      |       |        | X      | X       |                     |          |
| 2/19       |           |                  |            | X          |                      |       | X      |       |        | X      | X       |                     |          |
| 2/20       |           |                  |            | X          |                      | X     |        |       |        |        |         |                     |          |
| 2/21       |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |

| Group/Bird | Paralysis | Locomotive_Signs | Emaciation | Depression | Other Clinical Signs | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|------------|-----------|------------------|------------|------------|----------------------|-------|--------|-------|--------|--------|---------|---------------------|----------|
| 2/22       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/23       |           | X                |            | X          |                      |       |        |       |        |        |         |                     |          |
| 2/24       |           |                  |            | X          |                      |       |        |       |        |        | X       |                     |          |
| 2/25       |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |
| 2/26       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/27       |           |                  |            | X          |                      |       | X      |       | X      | X      |         |                     |          |
| 2/28       |           | X                |            | X          |                      | X     | X      |       |        |        |         |                     |          |
| 2/29       |           |                  |            | X          |                      | X     | X      |       |        |        | X       |                     |          |
| 2/30       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/31       |           |                  |            | X          |                      |       | X      |       |        |        | X       |                     |          |
| 2/32       |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |
| 2/33       |           |                  |            | X          |                      | X     | X      |       |        |        | X       |                     |          |
| 2/34       |           |                  |            | X          |                      |       | X      |       |        |        |         |                     |          |
| 2/35       |           | X                |            | X          |                      |       | X      |       |        | X      |         |                     |          |
| 4/1        |           |                  |            |            |                      |       |        |       |        | X      | X       |                     |          |
| 4/2        |           | X                |            | X          |                      |       |        |       |        | X      |         |                     |          |
| 4/3        |           |                  |            |            |                      |       | X      |       |        | X      | X       |                     |          |
| 4/4        |           | X                |            | X          |                      |       |        |       |        | X      | X       |                     |          |
| 4/5        |           | X                |            | X          |                      |       |        |       |        | X      | X       |                     |          |
| 4/6        |           |                  |            |            |                      |       |        |       |        | X      |         |                     |          |
| 4/7        |           |                  |            |            |                      |       |        |       |        |        | X       |                     |          |
| 4/8        |           |                  |            |            |                      |       |        |       |        |        | X       |                     |          |
| 4/9        |           |                  | X          |            |                      |       |        |       |        | X      | X       |                     |          |
| 4/10       |           |                  |            |            |                      | X     | X      |       |        |        | X       |                     |          |
| 4/11       |           | X                |            |            |                      |       |        |       | X      | X      | X       |                     |          |

|  |   |
|--|---|
| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Marek's disease virus, serotype 1   |
| <b>Study Purpose</b>                     | Demonstrate efficacy against very virulent Marek's disease virus (vvMDV)  |
| <b>Product Administration</b>            | One dose subcutaneously (SQ)  |
| <b>Study Animals</b>                     | One-day-old SPF chicks, 34-35 per group<br><br>Group 1: Vaccinated, challenged<br>Group 5: Placebo vaccinated, challenged (challenge control)<br>Group 6: Placebo vaccinated, placebo challenged (nonchallenge control)<br>Group 7: Vaccinated with serotype 3 Marek's vaccine and challenged (challenge severity group)  |
| <b>Challenge Description</b>             | Marek's virus (SR-1) RB1B strain at 4 days post vaccination   |
| <b>Interval observed after challenge</b> | Observed daily until necropsied at 45 days post-challenge (49 days post-hatch) to examine for gross lesions associated with Marek's disease   |
| <b>Results</b>                           | Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5).<br><br>Birds with clinical signs and/or observable lesions:<br>Group 1: 2/35<br>Group 5: 33/34<br>Group 6: 0/35<br>Group 7: 10/35<br><br>Requirements of 9 CFR 113.330(c)(4) & (5) were met.<br><br>Raw data on attached page. |
| <b>USDA Approval Date</b>                | July 16, 2013   |

Raw data shown below for birds classified as positive. All other birds normal.

| Group/Unit/Bird | Positive for Marek's | Comments   |
|-----------------|----------------------|--|
| 1/91/1          | Yes                  | Emaciated. NVL   |
| 1/91/11         | Yes                  |  |
| 5/81/1          | Yes                  | Emaciated. NVL   |
| 5/81/10         | Yes                  | Emaciated. MD tumors in kidney.  |
| 5/81/2          | Yes                  | NVL  |
| 5/81/3          | Yes                  | Emaciated. Kidneys   |
| 5/81/4          | Yes                  | NVL  |
| 5/81/5          | Yes                  | Emaciated. MD tumors in heart, muscle breast & kidneys.                    |
| 5/81/6          | Yes                  | MD tumors in liver, kidneys & gonads.                                      |
| 5/81/7          | Yes                  | Emaciated. MD tumors in kidney.  |
| 5/81/8          | Yes                  | Bird was down sick. Terminated. Emaciated. NVL.                            |
| 5/81/9          | Yes                  | MD tumors in liver & spleen  |
| 5/89/10         | Yes                  | MD tumors in kidneys.  |
| 5/89/11         | Yes                  | Heart, kidneys, gonads, breast muscle                                      |
| 5/89/12         | Yes                  | Kidneys  |
| 5/89/2          | Yes                  | MD tumors in liver, kidneys, spleen  |
| 5/89/3          | Yes                  | MD tumors in kidneys & gonad   |
| 5/89/4          | Yes                  | NVL  |
| 5/89/5          | Yes                  | Emaciated. NVL   |
| 5/89/6          | Yes                  | Emaciated. MD tumors in liver, gonads, kidneys, spleen.                    |
| 5/89/7          | Yes                  | Emaciated. MD tumors in liver, heart, spleen, kidneys & gonads.            |
| 5/89/8          | Yes                  | Emaciated. MD tumors in kidneys.   |
| 5/89/9          | Yes                  | Bird was down sick. Terminated. MD tumors in heart & gonads.               |
| 5/90/1          | Yes                  | MD tumors in gonads  |
| 5/90/10         | Yes                  | Terminated. Emaciated. Down with extended leg. MD tumors kidneys & gonads. |
| 5/90/11         | Yes                  | Terminated. Emaciated. MD in heart, spleen & kidneys.                      |
| 5/90/12         | Yes                  | Liver, spleen  |
| 5/90/2          | Yes                  | MD tumors in heart, liver, gonads, & kidneys                               |
| 5/90/3          | Yes                  | Emaciated. NVL.  |
| 5/90/4          | Yes                  | Emaciated. MD kidneys & heart.   |
| 5/90/5          | Yes                  | MD spleen  |
| 5/90/6          | Yes                  | MD tumors in liver & kidneys   |
| 5/90/7          | Yes                  | MD tumors in heart, kidneys & gonads                                       |



|                |     |  |
|----------------|-----|--|
| <b>5/90/8</b>  | Yes | MD tumors in spleen                          |
| <b>5/90/9</b>  | Yes | Emaciated. Tumors in kidneys & gonads.       |
| <b>7/37/1</b>  | Yes | Bird was down w/ NVL                         |
| <b>7/37/2</b>  | Yes | Emaciated. MD tumors in kidneys & gonads.    |
| <b>7/37/8</b>  | Yes | Gonads                                       |
| <b>7/38/1</b>  | Yes | Bird was down. NVL.                          |
| <b>7/38/2</b>  | Yes | NVL  |
| <b>7/39/1</b>  | Yes | MD tumor in gonads. Emaciated                |
| <b>7/39/12</b> | Yes |  |
| <b>7/39/2</b>  | Yes | MD tumor in proventriculus                   |
| <b>7/39/3</b>  | Yes | Bird down. MD tumors gonads & breast muscle. |
| <b>7/39/4</b>  | Yes | Bird down. Tumors in kidneys & gonads.       |

NVL – No visible lesions

MD – Marek's disease

|   |  |                  |                     |                         |                    |                       |
|---|--|------------------|---------------------|-------------------------|--------------------|-----------------------|
| <b>Study Type</b>   | Safety   |                  |                     |                         |                    |                       |
| <b>Pertaining to</b>  | ALL  |                  |                     |                         |                    |                       |
| <b>Study Purpose</b>  | Demonstrate safety of product under typical use conditions   |                  |                     |                         |                    |                       |
| <b>Product Administration</b>                                   | 1 dose by either the in ovo or subcutaneous route  |                  |                     |                         |                    |                       |
| <b>Study Animals</b>  | Commercial chicken eggs at 18 to 19 days of embryonation or chickens at one day of age. At each of the three sites, one group received the test vaccine and one group received vaccinations according to site standard practices. Hatchability for in ovo vaccinated groups was recorded. Animals were observed daily for mortality for 21 days. |                  |                     |                         |                    |                       |
| <b>Challenge Description</b>                                    | Not applicable   |                  |                     |                         |                    |                       |
| <b>Interval observed after challenge</b>                        | Not applicable   |                  |                     |                         |                    |                       |
| <b>Results</b>  | <b>Location</b>  | <b>Treatment</b> | <b>Total Placed</b> | <b>21 Day Mortality</b> | <b>% Mortality</b> | <b>% Hatchability</b> |
|   | 1  | In ovo           | 15,500              | 677                     | 4.4                | 74.1                  |
|   |  |                  | 15,500              | 561                     | 3.6                |                       |
|   | 1  | Control          | 27,200              | 367                     | 1.3                | 86.5                  |
|   | 2  | In ovo           | 20,000              | 291                     | 1.5                | 91.4                  |
|   | 2  | Control          | 20,000              | 277                     | 1.4                | 91.8                  |
|   | 3  | SQ               | 22,543              | 351                     | 1.6                | N/A                   |
|   | 3  | Control          | 22,540              | 756                     | 3.4                | N/A                   |
|   | N/A = not applicable   |                  |                     |                         |                    |                       |
| No adverse reactions attributable to the vaccine were recorded. |  |                  |                     |                         |                    |                       |
| <b>USDA Approval Date</b>                                       | July 2, 2018   |                  |                     |                         |                    |                       |