**Summary of Studies Supporting USDA Product Licensure**

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Zoetis Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA Vet Biologics Establishment Number</td>
<td>190</td>
</tr>
<tr>
<td>Product Code</td>
<td>12M5.E0</td>
</tr>
<tr>
<td>True Name</td>
<td>Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard &amp; Variant, Mass Type, Killed Virus</td>
</tr>
<tr>
<td>Tradename(s) / Distributor or Subsidiary (if different from manufacturer)</td>
<td>Not Listed - No distributor specified</td>
</tr>
<tr>
<td>Date of Compilation Summary</td>
<td>August 20, 2019</td>
</tr>
</tbody>
</table>

**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.
<table>
<thead>
<tr>
<th>Study Type</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertaining to</td>
<td>Infectious bursal disease virus</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>Demonstrate efficacy against standard infectious bursal disease in progeny</td>
</tr>
<tr>
<td>Product Administration</td>
<td></td>
</tr>
<tr>
<td>Study Animals</td>
<td>Chicken</td>
</tr>
<tr>
<td>Challenge Description</td>
<td>STC IBDV</td>
</tr>
<tr>
<td>Interval observed after challenge</td>
<td></td>
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<tr>
<td>Results</td>
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<td>USDA Approval Date</td>
<td>1 June 1995</td>
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<td><strong>Pertaining to</strong></td>
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<td><strong>Product Administration</strong></td>
<td>intramuscularly</td>
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<tr>
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<tr>
<td>Study Animals</td>
<td>Chickens</td>
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<td>Challenge Description</td>
<td>Avian Reovirus</td>
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<td>Interval observed after challenge</td>
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<td><strong>Results</strong></td>
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<td>Pertaining to</td>
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</tbody>
</table>

| USDA Approval Date   | 29 November 1994 |


**Study Type**  
Safety  
**Pertaining to**  
ALL  

**Study Purpose**  
To demonstrate safety under field conditions  

**Product Administration**  
One dose administered as an intramuscular or subcutaneous injection at 11 to 14 weeks of age.  

**Study Animals**  
Approximately 54,985 commercial broiler breeder pullets:  
Site A: Vaccinates: 9,477, Controls: 9,891  
Site B: Vaccinates: 8,405, Controls: 8,420  
Site C: Vaccinates: 9,479, Controls: 9,313  

**Challenge Description**  
Not applicable  

**Interval observed after vaccination**  
Birds were monitored daily for mortality through 21 days after vaccination.  

**Results**  

<table>
<thead>
<tr>
<th>Description</th>
<th>Site</th>
<th>Route</th>
<th>Total placed</th>
<th>% Mortality</th>
<th>Overall %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinates</td>
<td>Site A</td>
<td>IM</td>
<td>9,477</td>
<td>1.17*</td>
<td>1.01</td>
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<tr>
<td></td>
<td>Site B</td>
<td>SC</td>
<td>8,405</td>
<td>1.06</td>
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<tr>
<td></td>
<td>Site C</td>
<td>IM</td>
<td>9,479</td>
<td>0.73</td>
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<tr>
<td>Controls</td>
<td>Site A</td>
<td>IM</td>
<td>9,891</td>
<td>0.53</td>
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<td>8,420</td>
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<td>Site C</td>
<td>IM</td>
<td>9,313</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>

*Culling due to pre-existing breast blisters resulted in higher mortality and not attributed to vaccination as affirmed by licensee.  

No other adverse events were observed.  

**USDA Approval Date**  
8 November 2018