## Summary of Studies Supporting USDA Product Licensure

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Colorado Serum Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA Vet Biologics</td>
<td></td>
</tr>
<tr>
<td>Establishment Number</td>
<td>188</td>
</tr>
<tr>
<td>Product Code</td>
<td>2701.02</td>
</tr>
<tr>
<td>True Name</td>
<td>Pasteurella Multocida Bacterin</td>
</tr>
<tr>
<td>Tradename(s) / Distributor or Subsidiary (if different from manufacturer)</td>
<td>BunnyVac - No distributor specified</td>
</tr>
<tr>
<td>Date of Compilation Summary</td>
<td>October 28, 2021</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>Pasteurella Multocida Bacterin</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>To demonstrate efficacy against <em>Pasteurella multocida</em> (commonly referred to as “snuffles”), which is predominantly an upper respiratory disease.</td>
</tr>
<tr>
<td>Product Administration</td>
<td>Two doses injected subcutaneously 4 weeks apart for two different groups, Group A and Group B. Group C was a placebo-vaccinated group.</td>
</tr>
<tr>
<td>Study Animals</td>
<td>30 New Zealand White rabbits 12 weeks old, 10 rabbits per vaccination group. Both male and female. All seronegative for <em>Pasteurella multocida</em> antibody.</td>
</tr>
<tr>
<td>Challenge Description</td>
<td>21 days after the second vaccine dose was administered, all rabbits were challenged with live <em>Pasteurella multocida</em>.</td>
</tr>
<tr>
<td>Interval observed after challenge</td>
<td>All rabbits were observed for 15 days post-challenge.</td>
</tr>
<tr>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>Summary of Observations</td>
<td>Group A (Vaccine)</td>
</tr>
<tr>
<td>Mortality* S/T</td>
<td>10/10</td>
</tr>
<tr>
<td><strong>Mortality</strong>&lt;sup&gt;*&lt;/sup&gt; = Survivors/Total. A rabbit was considered affected if mortality was due to <em>Pasteurella multocida</em>.</td>
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</tr>
<tr>
<td>Raw data on the following page.</td>
<td></td>
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<td>USDA Approval Date</td>
<td>February 6, 2013</td>
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**GROUP C (Placebo) POST CHALLENGE MORTALITY**

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<tr>
<th>No. - ID</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Day 8</th>
<th>Day 9</th>
<th>Day 10</th>
<th>Day 11</th>
<th>Day 12</th>
<th>Day 13</th>
<th>Day 14</th>
<th>Day 15</th>
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<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
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</tbody>
</table>

Survive = S  
D = Dead

**GROUP C (Placebo) POST CHALLENGE MORTALITY**

<table>
<thead>
<tr>
<th>Post-Challenge</th>
<th>Dead/Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>0/10</td>
</tr>
<tr>
<td>Day 2</td>
<td>0/10</td>
</tr>
<tr>
<td>Day 3</td>
<td>0/10</td>
</tr>
<tr>
<td>Day 4</td>
<td>1/10</td>
</tr>
<tr>
<td>Day 5</td>
<td>2/10</td>
</tr>
<tr>
<td>Day 6</td>
<td>3/10</td>
</tr>
<tr>
<td>Day 7</td>
<td>5/10</td>
</tr>
<tr>
<td>Day 8</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 9</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 10</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 11</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 12</td>
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</tr>
<tr>
<td>Day 13</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 14</td>
<td>6/10</td>
</tr>
<tr>
<td>Day 15</td>
<td>6/10</td>
</tr>
<tr>
<td>Study Type</td>
<td>Safety</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pertaining to</td>
<td>Pasteurella Multocida Bacterin</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>To demonstrate safety of Pasteurella Multocida Bacterin under typical use conditions.</td>
</tr>
<tr>
<td>Product Administration</td>
<td>Two doses injected subcutaneously 3-4 weeks apart</td>
</tr>
<tr>
<td>Study Animals</td>
<td>155 New Zealand White rabbits and 153 California breed rabbits at three different locations.</td>
</tr>
<tr>
<td>Challenge Description</td>
<td>NA</td>
</tr>
<tr>
<td>Interval Observed after Vaccination</td>
<td>All rabbits were observed at 15 minutes and 2 hours on day of vaccination, daily for 14 days post-vaccination</td>
</tr>
<tr>
<td>Results</td>
<td>Location  No. Vaccinates  Adverse Reactions</td>
</tr>
<tr>
<td></td>
<td>PV-1         PV-2</td>
</tr>
<tr>
<td></td>
<td>1 70 NZ, 28 C    0/98 * 0/96</td>
</tr>
<tr>
<td></td>
<td>2 85 NZ, 0 C     0/85   0/85</td>
</tr>
<tr>
<td></td>
<td>3 0 NZ, 125 C    0/125   0/125</td>
</tr>
</tbody>
</table>

Key: NZ = New Zealand, C = California, PV=Post-Vaccination

* Two NZ rabbits died during the study and licensee determined that both deaths were not related to the study or the vaccine.

USDA Approval Date November 20, 2012