Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	4865.01
True Name	Encephalomyelitis Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Encevac-T - Merck Animal Health
Date of Compilation Summary	December 19, 2017

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>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Clostridum tetani</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against C. tetani</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously.</td></tr>
<tr><td>Study Animals</td><td>Ten guinea pigs (5 females and 5 males, 450-550g)</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Six weeks after vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of C. tetani was demonstrated in laboratory animals according to 9CFR 113.114(c).

Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool.

<table><tr><th>Pooled Guinea Pig Antitoxin titer (A.U./mL)</th></tr><tr><td>2.082</td></tr></table></td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Eastern Equine Encephalomyelitis (EEE)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against EEE</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>14 days post 2nd vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of EEE was demonstrated in laboratory animals according to 9CFR 113.207(b).

Satisfactory test result is a Virus Neutralization Titer of ≥ 1:40 in at least 9 out of 10 vaccinates (2nd stage - at least 17 out of 20 vaccinates).

<table>
<tr><th>Treatment group</th><th>Results</th><th>Test Disposition</th></tr>
<tr><td>Vaccinates</td><td>17/20 ≥ 1:40</td><td rowspan="2">Satisfactory</td></tr>
<tr><td>Controls</td><td>2/2 <1:4</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Western Equine Encephalomyelitis (WEE)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against WEE</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>14 days post 2nd vaccination, guinea pigs were bled for serological testing.</td></tr>
<tr><td>Results</td><td>Efficacy of WEE was demonstrated in laboratory animals according to 9CFR 113.207(b).

Satisfactory test result is a Virus Neutralization Titer of ≥ 1:40 in at least 9 of the vaccinates.

<table>
<tr><th>Treatment group</th><th>Results</th><th>Test Disposition</th></tr>
<tr><td>Vaccinates</td><td>9/10 ≥ 1:40</td><td rowspan="2">Satisfactory</td></tr>
<tr><td>Controls</td><td>2/2 <1:4</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>June 15, 2010</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>298 horses received 2 doses intramuscularly 3 to 4 weeks apart for primary immunization. 254 horses received 1 dose intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>552 horses of various ages, breeds and sex in 5 different states. 177 horses were 4-months of age or younger at the time of the initial vaccination.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed immediately following vaccination and then daily for 3 days post-vaccination</td></tr>
<tr><td>Results</td><td>Doses are reported due to difference in vaccination schedule.

<table>
<tr><th>Score</th><th># of Cases</th><th>% of Total</th></tr>
<tr><td>0</td><td>820</td><td>96.47</td></tr>
<tr><td>1</td><td>25</td><td>2.94</td></tr>
<tr><td>2</td><td>3</td><td>0.35</td></tr>
<tr><td>3</td><td>2</td><td>0.24</td></tr>
<tr><td>4</td><td>0</td><td>0</td></tr>
<tr><td>5</td><td>0</td><td>0</td></tr>
</table>
Total # of Doses administered = 850

Score Overview:
0 – No reaction
1 – Localized swelling at or near the injection site, which is not visible; detectable only by palpation. Not clinically significant.
2 – Localized visible swelling at or near the injection site. Not painful.
3 – Localized visible swelling at or near the injection site. Raised, circumscribed and painful.
4 – Visible diffused swelling involving a substantial area around the injection site. Very painful and hot. Horse is stiff and/or reluctant to move.
5 – Generalized or systemic reaction, including anaphylaxis or elevated temperature.</td></tr>
<tr><td>USDA Approval Date</td><td>February 8, 2006</td></tr>
</table>