Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1905.23
True Name	Rabies Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	EquiRab - Merck Animal Health Prestige EquiRab - Merck Animal Health
Date of Compilation Summary	April 10, 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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Rabies Virus (RV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against Rabies virus 14 months after vaccination.</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly (IM)</td></tr>
<tr><td>Study Animals</td><td>26 vaccinates and 11 controls horses were used at 4 months of age.</td></tr>
<tr><td>Challenge Description</td><td>11 vaccinates and 5 control horse were challenged with Rabies virus 14 months post vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Horses were observed daily for 90 days post-challenge.</td></tr>
<tr><td>Results</td><td>Efficacy was demonstrated according to 9CFR 113.209(b).

<table>
<tr><th>Group</th><th>Number of Animals</th><th>Number Challenged</th><th>Number of Deaths attributed to RV by DFA</th></tr>
<tr><td>Vaccinates</td><td>26</td><td>11</td><td>0</td></tr>
<tr><td>Controls</td><td>11</td><td>5</td><td>4</td></tr>
</table>
DFA is direct fluorescent antibody titer

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>March 1, 2006</td></tr>
</table>

Horse ID #	Treatment Group	Sex	Status	Horse ID #	Treatment Group	Sex	Status
273	Vaccinate	M	Survived	278	Control	F	Survived
285	Vaccinate	F	Survived	309	Control	M	Euthanized**
286	Vaccinate	F	Survived	312	Control	M	Dead
288	Vaccinate	F	Survived	313	Control	F	Dead
289	Vaccinate	F	Dead*	315	Control	M	Euthanized**
290	Vaccinate	M	Survived				
292	Vaccinate	M	Survived				
293	Vaccinate	F	Survived				
295	Vaccinate	M	Survived				
300	Vaccinate	M	Survived				
305	Vaccinate	F	Survived				
Protection 100% (10/10)				Rabies incidence 80% (4/5)			

* The animal died on day 61 post-challenge. Cause of death was determined to be not related to rabies. The absence of rabies virus was confirmed by direct fluorescent antibody titer (DFA) .

** Euthanized following the neurological signs suggestive of rabies.

<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>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>992 horses from 3 states. 413 horses were 4 months of age or younger at time of the intial 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>
<table>
<tr><th>Score</th><th># of Reactions</th><th>% of Total</th></tr>
<tr><td>0</td><td>969</td><td>97.68</td></tr>
<tr><td>1</td><td>15</td><td>1.51</td></tr>
<tr><td>2</td><td>8</td><td>0.81</td></tr>
<tr><td>3</td><td>0</td><td>0</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>
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.

All swellings resolved by 4 days post-vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>October 23, 2007</td></tr>
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