Summary of Studies Supporting USDA Product Licensure

Establishment Name	Huvepharma, Inc.
USDA Vet Biologics Establishment Number	605
Product Code	1U11.R0
True Name	Clostridium Perfringens Type A Vaccine, Live Salmonella Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Avert NE - No distributor specified
Date of Compilation Summary	November 03, 2020

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>Clostridium perfringens type A</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against necrotic enteritis due to Clostridium perfringens Type A</td></tr>
<tr><td>Product Administration</td><td>Initial dose administered by coarse spray at day-of-age (Study Day 1) and second dose administered in drinking water at 11 days of age (Study Day 11)</td></tr>
<tr><td>Study Animals</td><td>Group 1: Non-vaccinated, non-challenged sentinel control
Group 2: Non-vaccinated, Eimeria maxima treated control
Group 3: Placebo vaccinated, Eimeria treated and Clostridium challenge
Group 4: Product vaccinated (Vaccine), Eimeria treated and Clostridium challenge</td></tr>
<tr><td>Challenge Description</td><td>Chickens were treated with Eimeria maxima oocysts on Study Day 14 and challenged with Clostridium perfringens on Study Days 19, 20 and 21</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed twice daily for 10 days after challenge. Birds that succumbed during the observation period were evaluated for intestinal lesions. Remaining birds were humanely euthanized on Study Day 28.</td></tr>
<tr><td>Results</td><td>Mortality after Challenge due to Necrotic Enteritis

<table>
<tr><th>Treatment Group</th><th>Number Chickens</th><th>Vaccine</th><th>Eimeria inoculation</th><th>C. perfringens challenge</th><th>Results</th></tr>
<tr><td>1</td><td>16</td><td>None</td><td>-</td><td>-</td><td>0/14</td></tr>
<tr><td>2</td><td>80</td><td>None</td><td>+</td><td>-</td><td>0/75</td></tr>
<tr><td>3</td><td>192</td><td>Placebo</td><td>+</td><td>+</td><td>58/180*</td></tr>
<tr><td>4</td><td>192</td><td>Vaccine</td><td>+</td><td>+</td><td>16/173*</td></tr>
</table>
* Death due to necrotic enteritis (confirmed by necropsy) per total birds challenged</td></tr>
<tr><td>USDA Approval Date</td><td>June 17, 2019</td></tr>
</table>

Treatment Group	Chickens Challenged	Mortality Due to Necrotic Enteritis by Day After Challenge									
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
3	180	0	0	24	16	14	4	0	0	0	0
4	173	0	0	10	2	3	1	0	0	0	0

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Clostridium perfringens type A</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against necrotic enteritis due to Clostridium perfringens Type A</td></tr>
<tr><td>Product Administration</td><td>One dose administered by course spray at day of age (Study Day 1)</td></tr>
<tr><td>Study Animals</td><td>Group 1: Non-vaccinated, non-challenged sentinel control
Group 2: Non-vaccinated, Eimeria maxima treated control
Group 3: Placebo vaccinated, Eimeria treated and Clostridium challenge
Group 4: Product vaccinated (Vaccine), Eimeria treated and Clostridium challenge</td></tr>
<tr><td>Challenge Description</td><td>Chickens were treated with Eimeria maxima oocysts on Study Day 14 and challenged with Clostridium perfringens on Study Day 19</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed twice daily for 10 days after challenge. Birds that succumbed during the observation period were evaluated for intestinal lesions. Remaining birds were humanely euthanized on Study Day 28.</td></tr>
<tr><td>Results</td><td>Mortality after Challenge due to Necrotic Enteritis

<table>
<tr><th>Treatment Group</th><th>Number Chickens</th><th>Vaccine</th><th>Eimeria inoculation</th><th>C. perfringens challenge</th><th>Results</th></tr>
<tr><td>1</td><td>16</td><td>None</td><td>-</td><td>-</td><td>0/15</td></tr>
<tr><td>2</td><td>80</td><td>None</td><td>+</td><td>-</td><td>0/79</td></tr>
<tr><td>3</td><td>192</td><td>Placebo</td><td>+</td><td>+</td><td>68/191*</td></tr>
<tr><td>4</td><td>192</td><td>Vaccine</td><td>+</td><td>+</td><td>25/191*</td></tr>
</table>
* Death due to necrotic enteritis (confirmed by necropsy) per total birds challenged</td></tr>
<tr><td>USDA Approval Date</td><td>April 30, 2020</td></tr>
</table>

Treatment Group	Chickens Challenged	Mortality Due to Necrotic Enteritis by Day After Challenge									
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
3	191	0	35	32	1	0	0	0	0	0	0
4	191	0	12	13	0	0	0	0	0	0	0

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All fractions</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses: Administered by coarse spray at day of age and at 14 days of age via drinking water</td></tr>
<tr><td>Study Animals</td><td>Commercial broiler chickens day of age</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Chickens were observed daily for 21 days after vaccination.</td></tr>
<tr><td>Results</td><td>Total Mortality for Vaccinates and Controls*
<table>
<tr><th>Site</th><th>Treatment</th><th>Number of Chickens</th><th>Mortality</th><th>Percent Mortality</th></tr>
<tr><td>1</td><td>Vaccinates</td><td>63,900</td><td>1378</td><td>2.16</td></tr>
<tr><td></td><td>Controls</td><td>64,160</td><td>2454</td><td>3.82</td></tr>
<tr><td>2</td><td>Vaccinates</td><td>43,600</td><td>641</td><td>1.47</td></tr>
<tr><td></td><td>Controls</td><td>44,220</td><td>1031</td><td>2.33</td></tr>
</table>
*Mortality of controls at each site is the average mortality of five previous flocks at the same site.

No adverse reactions attributable to the vaccine were observed.</td></tr>
<tr><td>USDA Approval Date</td><td>09/22/2020</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All fractions</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>One dose: Administrated by coarse spray at day of age</td></tr>
<tr><td>Study Animals</td><td>Commercial broiler chickens day of age</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Chickens were observed daily for 21 days after vaccination.</td></tr>
<tr><td>Results</td><td>Total Mortality for Vaccinates and Controls*
<table>
<tr><th>Site</th><th>Treatment</th><th>Number of Chickens</th><th>Mortality</th><th>Percent Mortality</th></tr>
<tr><td>1</td><td>Vaccinates</td><td>76,768</td><td>1261</td><td>1.64</td></tr>
<tr><td></td><td>Controls</td><td>78,346</td><td>1367</td><td>1.75</td></tr>
<tr><td>2</td><td>Vaccinates</td><td>60,000</td><td>1994</td><td>3.32</td></tr>
<tr><td></td><td>Controls</td><td>60,680</td><td>1667</td><td>2.75</td></tr>
</table>
*Mortality of controls at each site is the average mortality of five previous flocks at the same site.

No adverse reactions attributable to the vaccine were observed.</td></tr>
<tr><td>USDA Approval Date</td><td>09/22/2020</td></tr>
</table>