Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	10M1.10
True Name	Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	January 10, 2022

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.

Study Type	Efficacy
Pertaining to	Avian Encephalomyelitis Virus (AEV) and Fowl Pox Virus (FPV)
Study Purpose	Demonstrate efficacy against challenge with virulent AEV and FPV.
Product Administration	One dose administered through wing-web at 8 weeks of age
Study Animals	Eight-week-old specific pathogen free chickens divided into 5 groups: Group 1: 30 chickens vaccinated and challenged with virulent AEV Group 2: 30 chickens vaccinated and challenged with virulent FPV Group 3: 30 chickens sham vaccinated and challenged with virulent AEV (positive control) Group 4: 30 chickens sham vaccinated and challenged with virulent FPV (positive control) Group 5: 20 chickens left as sentinels (negative control) and not challenged
Challenge Description	Chickens were challenged at 3 weeks post-vaccination using the virulent strains of AEV and FPV obtained from USDA
Interval observed after challenge	The AEV challenged chickens were observed daily for 21 days post-challenge for AEV induced clinical signs and/or mortality. The FPV challenged chickens were observed at 2 to 4 days interval for 10 days post-challenge for clinical signs of FPV infection.
Results	Vaccinates and controls were evaluated in terms of AEV and FPV induced specific clinical signs and/or mortality. Birds with positive clinical signs and/or mortality: Group 1: 1/30 positive for AEV Group 2: 0/30 positive for FPV Group 3: 30/30 positive for AEV Group 4: 30/30 positive for FPV Group 5: 0/20 positive for either AEV or FPV The requirements of 9 CFR 113.325 were met for AEV. The requirements of 9 CFR 113.326 were met for FPV. See table on attached page
USDA Approval Date	09/24/2012

Table below is for the birds classified as positive for AEV and FPV induced clinical signs and/or mortality. All other birds remained normal.

Group	Bird ID	AEV clinical signs	AEV mortality	Group	Bird ID	FPV clinical signs
1	250	x		4	17	x
3	36	x		4	19	x
3	39	x		4	28	x
3	42	x		4	32	x
3	52	x		4	34	x
3	53	x		4	40	x
3	68	x		4	47	x
3	69	x	x	4	49	x
3	78	x		4	54	x
3	79	x	x	4	61	x
3	81	x	x	4	77	x
3	92	x		4	82	x
3	96	x		4	84	x
3	242	x		4	86	x
3	246	x		4	94	x
3	257	x		4	95	x
3	259	x	x	4	241	x
3	263	x	x	4	248	x
3	266	x	x	4	252	x
3	269	x	x	4	260	x
3	281	x		4	264	x
3	282	x	x	4	271	x
3	295	x	x	4	273	x
3	299	x		4	285	x
3	341	x	x	4	286	x
3	348	x	x	4	290	x
3	356	x		4	291	x
3	366	x	x	4	293	x
3	369	x	x	4	331	x
3	371	x	x	4	358	x
3	372	x				

No pox virus induced mortality was seen in any of the challenged birds.

<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>Single dose administered through wing-web route</td></tr>
<tr><td>Study Animals</td><td>Commercial layer type chickens aged 8 to 11 weeks and representing three independent study sites were used. For site 1: 74,684 vaccinates and 75,705 controls. For site 2: 39,766 vaccinates and 40,147 controls. For site 3: 71,198 vaccinates and 68,208 controls.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Chickens were observed daily for mortality and adverse reactions up to 3 weeks post vaccination</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th rowspan="2">Site</th><th rowspan="2">Group</th><th rowspan="2">Total Birds</th><th colspan="3">Average daily mortality (%)</th><th rowspan="2">Total Mortality (%)</th></tr>
<tr><th>Week 1</th><th>Week 2</th><th>Week 3</th></tr>
<tr><td rowspan="2">1</td><td>Vaccine</td><td>74,684</td><td>0.01</td><td>0.01</td><td>0.02</td><td>0.38</td></tr>
<tr><td>Control</td><td>75,705</td><td>0.01</td><td>0.01</td><td>0.01</td><td>0.32</td></tr>
<tr><td rowspan="2">2</td><td>Vaccine</td><td>39,766</td><td>0.01</td><td>0.01</td><td>0.01</td><td>0.70</td></tr>
<tr><td>Control</td><td>40,147</td><td>0.01</td><td>0.00</td><td>0.01</td><td>0.48</td></tr>
<tr><td rowspan="2">3</td><td>Vaccine</td><td>71,198</td><td>0.03</td><td>0.04</td><td>0.15</td><td>2.56</td></tr>
<tr><td>Control</td><td>68,208</td><td>0.02</td><td>0.01</td><td>0.01</td><td>0.31</td></tr>
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No adverse reactions attributable to the vaccine were reported from any site.
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<tr><td>USDA Approval Date</td><td>08/21/2013</td></tr>
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