Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	1881.10
True Name	Pigeon Pox Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	January 11, 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	Fowl Pox Virus (FPV)
Study Purpose	Demonstrate efficacy against challenge with a virulent strain of 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 3 groups: Group 1: 32 chickens vaccinated and challenged with virulent FPV Group 2: 32 chickens sham vaccinated and challenged with virulent FPV (positive control) Group 3: 21 chickens left as sentinels (negative control) and not challenged
Challenge Description	Chickens were challenged at 3 weeks post-vaccination using a virulent strain of FPV obtained from USDA
Interval observed after challenge	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 FPV induced specific clinical signs. Birds with positive clinical signs and/or mortality: Group 1: 0/32 positive for FPV Group 2: 32/32 positive for FPV Group 3: 0/21 positive for FPV The requirements of 9 CFR 113.326 were met for FPV. See table on attached page
USDA Approval Date	06/25/2012

Table below is for the birds classified as positive for FPV induced clinical signs. All other birds remained normal.

Group	Bird ID	FPV clinical signs
2	384	x
2	452	x
2	462	x
2	478	x
2	486	x
2	492	x
2	516	x
2	573	x
2	584	x
2	609	x
2	639	x
2	691	x
2	696	x
2	702	x
2	706	x
2	728	x
2	740	x
2	760	x
2	777	x
2	805	x
2	816	x
2	843	x
2	853	x
2	855	x
2	856	x
2	861	x
2	897	x
2	907	x
2	931	x
2	971	x
2	979	x
2	999	x

No 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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