



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Arko Laboratories Ltd.
USDA Vet Biologics Establishment Number	337
Product Code	10C5.11
True Name	Avian Paramyxovirus Vaccine, Type 1, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	January 25, 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.**

<b>Study Type</b>	Safety																								
<b>Pertaining to</b>	all																								
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions.																								
<b>Product Administration</b>	2 doses administered at 2 week intervals by subcutaneous administration.																								
<b>Study Animals</b>	60 pigeons, ranging from 5 weeks to 10 years old.																								
<b>Challenge Description</b>	NA																								
<b>Interval observed after challenge</b>	Birds were observed during and after each vaccination and daily through 7 days after the second vaccination.																								
<b>Results</b>	<p style="text-align: center;">Frequency of Adverse Events</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Site #1</th> <th>Site #2</th> <th>Site #3</th> </tr> <tr> <th></th> <th>N=20</th> <th>N=20</th> <th>N=20</th> </tr> </thead> <tbody> <tr> <td>Injection Site Swelling</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Respiratory Distress</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Pain on Injection</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td>No Adverse Events</td> <td style="text-align: center;">20</td> <td style="text-align: center;">20</td> <td style="text-align: center;">20</td> </tr> </tbody> </table> <p>Due to an exceptional need for this product in the field and a history of the organism being used in autogenous products, testing in 60 pigeons was deemed acceptable to support conditional licensure. Additional data will be evaluated prior to issuing a full license.</p>		Site #1	Site #2	Site #3		N=20	N=20	N=20	Injection Site Swelling	0	0	0	Respiratory Distress	0	0	0	Pain on Injection	0	0	0	No Adverse Events	20	20	20
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<b>USDA Approval Date</b>	December 20, 2017																								