Summary of Studies Supporting USDA Product Licensure

Establishment Name	Arko Laboratories Ltd.
USDA Vet Biologics Establishment Number	337
Product Code	2825.00
True Name	Salmonella Typhimurium Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	NUSAL KM-1 - No distributor specified
Date of Compilation Summary	January 05, 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>Salmonella Typhimurium</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate effectiveness against Salmonella Typhimurium.</td></tr>
<tr><td>Product Administration</td><td>Two doses, three weeks apart subcutaneously.</td></tr>
<tr><td>Study Animals</td><td>30 pigeons about 6 weeks of age, 15 vaccinates and 15 controls.</td></tr>
<tr><td>Challenge Description</td><td>Salmonella typhimurium administered 10 days post 2nd vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigeons observed daily for 21 days post challenge for clinical signs. Cloacal swabs were collected for Salmonella culture starting at 7 days post-challenge. Liver, spleen, cloaca, and tissues were examined for lesions and swabs collected for Salmonella culture.</td></tr>
<tr><td>Results</td><td>A pigeon was considered affected if shedding (Salmonella identified on culture), clinical signs, or lesions were observed.

Summary of results
<table><tr><th rowspan="2">Group</th><th rowspan="2">#Birds</th><th rowspan="2">Shedding</th><th colspan="3">Clinical Signs[1]</th></tr><tr><th>1 week</th><th>2 weeks</th><th>3 weeks</th></tr><tr><td>Vaccinates</td><td>15</td><td>0/15</td><td>0/15</td><td>0/15</td><td>0/15</td></tr><tr><td>Controls</td><td>15</td><td>11/15</td><td>3/15</td><td>3/15</td><td>8/15</td></tr></table>[1] Clinical signs consisted of stiffness of legs or wings or respiratory rales

Raw data are below:</td></tr>
<tr><td>USDA Approval Date</td><td>01/08/2013</td></tr>
</table>

Table. For Culture or Clinical Signs, a 1 indicates positive at any observation time; a 0 indicates negative at all observation times. For Lesion, the number indicates the size of the lesion by category.

Group	Bird ID	Lesion[1]	Culture	Clinical Signs Observed	Clinical Signs First Day[2]	Clinical Signs Last Day[3]
A (Vaccinates)	16	0	0	0	–	–
	168	0	0	0	–	–
	2	0	0	0	–	–
	20	0	0	0	–	–
	22K	0	0	0	–	–
	23	0	0	0	–	–
	4	0	0	0	–	–
	48	0	0	0	–	–
	5K	0	0	0	–	–
	10	1	0	0	–	–
	13	1	0	0	–	–
	24	0	0	0	–	–
	18	1	0	0	–	–
	19	1	0	0	–	–
	268	1	0	0	–	–
B (Controls)	1	0	1	0	–	–
	12	1	0	0	–	–
	167	1	0	0	–	–
	35	1	1	1	5	17
	36	1	1	1	7	20
	14	2	1	1	14	20
	15	2	1	1	4	19
	21	2	1	0	–	–
	22	2	1	0	–	–
	3	2	0	0	–	–
	8	2	0	0	–	–
	11	3	1	1	14	20
	17	3	1	1	14	19
	25	3	1	1	14	20
	5	3	1	1	14	20

[1]Lesions were scored by size
0 None
1 Mild (1-2 cm)
2 Moderate (3-4 cm)
3 Extensive (over 4 cm)

[2]First day after challenge clinical signs were observed

[3]Last day after challenge clinical signs were observed

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	Two doses at a three week interval
Study Animals	45 pigeons of various ages and breeds.
Challenge Description	None
Interval observed after vaccination	28 days
Results	Study Site No. of Vaccinates Results 1 25 no reactions to vaccine 2 20 no reactions to vaccine All birds completed the study and no adverse events were reported. The safety of this product was further demonstrated by acceptable use in approximately 5000 additional pigeons—data not available.
USDA approval date	March 7, 2013