Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1555.R8
True Name	Feline Leukemia Vaccine, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac NXT FeLV - Merck Animal Health Nobivac NXT FeLV - No distributor specified
Date of Compilation Summary	September 09, 2024

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>Feline leukemia virus (FeLV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against FeLV 12 months after vaccination</td></tr>
<tr><td>Product Administration</td><td>Two doses administered by the subcutaneous route three weeks apart</td></tr>
<tr><td>Study Animals</td><td>Cats, 8 weeks of age at time of 1st vaccination; 18 vaccinates, 13 controls</td></tr>
<tr><td>Challenge Description</td><td>All cats were challenged with FeLV at 421, 424, 426 and 428 days after the 2nd vaccination. All cats were administered an immunosuppressive on the last day of challenge.</td></tr>
<tr><td>Interval observed after challenge</td><td>Clinical signs were observed daily, and blood samples were collected at weekly intervals from 3 to 12 weeks post-challenge.</td></tr>
<tr><td>Results</td><td>A cat was considered affected if FeLV antigenemia (detected by p27 in serum) was present for 3 consecutive weeks or on 5 or more occasions, consecutive or not, between the 3rd and 12th week post-challenge.

Summary of FeLV antigenemia results:
<table>
<tr><td>Group</td><td>Positive</td><td>Negative</td></tr>
<tr><td>Vaccinates</td><td>5</td><td>13</td></tr>
<tr><td>Controls</td><td>11</td><td>2</td></tr>
</table>
Raw data are shown below.</td></tr>
<tr><td>USDA Approval Date</td><td>January 3, 2020</td></tr>
</table>

Table 1: FeLV Antigenemia Results Post-Challenge

Animal ID	Treatment Group	Weeks Post-Challenge									
		3	4	5	6	7	8	9	10	11	12
FAQ1	FeLV Vaccinates	-	-	-	-	-	-	-	-	-	-
FAQ2		-	-	-	-	-	-	-	-	-	-
FAR2		+	-	-	-	-	-	-	-	-	-
FAR6		-	-	-	-	-	-	-	-	-	-
FAT1		-	-	-	-	-	-	-	-	-	-
FAV3		+	+	+	-	-	-	-	-	-	-
FAW1		-	-	-	-	-	-	-	-	-	-
FAX1		+	-	-	-	-	-	-	-	-	-
MBF2		+	+	+	+	+	+	+	+	+	+
MBG1		+	+	+	+	+	+	+	+	+	+
MBH1		-	-	-	-	-	-	-	-	-	-
MBI2		-	-	-	-	-	-	-	-	-	-
MBI7		-	-	-	-	-	-	-	-	-	-
MBJ2		+	+	+	+	+	+	+	+	+	+
MBJ3		-	-	-	-	-	-	-	-	-	-
MBJ5		+	+	+	+	+	+	+	+	+	+
MBL2		-	-	-	-	-	-	-	+	-	-
MBL3		-	+	+	-	-	-	-	-	-	-
FAQ3	Non-Vaccinated Controls	+	+	+	+	+	+	+	+	+	+
FAR1		+	+	+	+	+	NA	NA	NA	NA	NA
FAT3		+	+	+	+	+	+	+	+	+	+
FAV2		+	+	-	-	-	-	-	-	-	-
FAW3		+	+	+	+	+	+	+	+	+	+
FAX4		+	+	+	+	+	+	+	+	+	+
MBF3		+	+	+	+	+	+	NA	+	NA	+
MBG2		+	+	+	+	+	+	+	+	+	+
MBH2		+	+	+	+	+	+	+	NA	NA	+
MBI1		-	-	-	-	-	-	-	-	-	-
MBI9		+	+	+	+	+	+	+	+	+	+
MBJ1		+	+	+	+	+	+	+	+	+	+
MBL1		+	+	+	+	+	+	+	+	+	+

+ positive for FeLV antigen
- negative for FeLV antigen
NA sample not collected due to previous confirmation of persistent antigenemia and fractious nature of cat

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Feline leukemia virus (FeLV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against FeLV 24 months after vaccination</td></tr>
<tr><td>Product Administration</td><td>Two doses administered by the subcutaneous route three weeks apart</td></tr>
<tr><td>Study Animals</td><td>Cats, 7-8 weeks of age at time of 1st vaccination; 18 vaccinates, 15 controls</td></tr>
<tr><td>Challenge Description</td><td>All cats were challenged with FeLV at 734, 737, 739 and 741 days after the 2nd vaccination. All cats were administered an immunosuppressive on the last day of challenge.</td></tr>
<tr><td>Interval observed after challenge</td><td>Clinical signs were observed daily, and blood samples were collected at weekly intervals from 3 to 12 weeks post-challenge.</td></tr>
<tr><td>Results</td><td>A cat was considered affected if FeLV antigenemia (detected by p27 in serum) was present for 3 consecutive weeks or on 5 or more occasions, consecutive or not, between the 3rd and 12th week post-challenge.

Summary of FeLV antigenemia results:
<table>
<tr><td>Group</td><td>Positive</td><td>Negative</td></tr>
<tr><td>Vaccinates</td><td>4</td><td>14</td></tr>
<tr><td>Controls</td><td>14</td><td>1</td></tr>
</table>
Raw data are shown below.</td></tr>
<tr><td>USDA Approval Date</td><td>December 22, 2020</td></tr>
</table>

Table 1: FeLV Antigenemia Results Post-Challenge

Animal ID	Treatment Group	Weeks Post-Challenge									
		3	4	5	6	7	8	9	10	11	12
FBL4	FeLV Vaccinates	-	-	-	-	-	-	-	-	-	-
FBL6		-	-	-	-	-	-	-	-	-	-
FBN2		+	+	-	-	-	-	-	-	-	-
FBO4		-	-	-	-	-	-	-	-	-	-
FBO5		-	-	-	-	-	-	-	-	-	-
FBQ1		-	-	-	-	-	-	-	-	-	-
FBQ5		+	+	+	+	NA	NA	NA	NA	NA	+
FBR1		-	-	-	-	-	-	-	-	-	-
FBT1		+	+	+	+	NA	NA	NA	NA	NA	+
FBT2		+	+	-	-	-	-	-	-	-	-
FBU2		+	+	+	NA	NA	NA	NA	NA	NA	+
FBU3		+	+	+	+	NA	NA	NA	NA	NA	+
FBV2		-	-	-	-	-	-	-	-	-	-
FBW4		-	-	+	-	-	-	-	-	-	-
FBW5		-	-	-	-	-	-	-	-	-	-
MBW4		-	-	-	-	-	-	-	-	-	-
MBZ3		-	-	-	-	-	-	-	-	-	-
MCB1		-	-	-	-	-	-	-	-	-	-
FBL7	Non-Vaccinated Controls	+	+	+	NA	NA	NA	NA	NA	NA	+
FBN1		+	+	+	+	NA	NA	NA	NA	NA	+
FBO1		+	+	+	+	NA	NA	NA	NA	NA	+
FBQ2		+	+	+	+	NA	NA	NA	NA	NA	+
FBQ4		+	+	+	+	NA	NA	NA	NA	NA	+
FBR2		-	-	-	-	-	-	-	-	-	-
FBT3		+	+	+	+	NA	NA	NA	NA	NA	+
FBU1		+	+	+	NA	NA	NA	NA	NA	NA	+
FBU4		+	+	+	NA	NA	NA	NA	NA	NA	+
FBV1		+	+	+	+	NA	NA	NA	NA	NA	+
FBW1		+	+	+	+	+	NA	NA	NA	NA	+
FBW2		+	+	+	+	NA	NA	NA	NA	NA	+
MBW1		+	+	+	+	NA	NA	NA	NA	NA	+
MBZ2		+	+	+	+	NA	NA	NA	NA	NA	+
MCB4		+	+	+	+	NA	NA	NA	NA	NA	+

+ positive for FeLV antigen
- negative for FeLV antigen
NA sample not collected due to previous confirmation of persistent antigenemia

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Feline leukemia virus (FeLV)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against FeLV</td></tr>
<tr><td>Product Administration</td><td>Two doses administered by the subcutaneous route three weeks apart</td></tr>
<tr><td>Study Animals</td><td>Cats, 8 weeks of age at time of 1st vaccination; 20 vaccinates, 20 controls</td></tr>
<tr><td>Challenge Description</td><td>Cats were challenged with FeLV 4-weeks after the 2nd vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Clinical signs were observed daily, and blood samples were collected at weekly intervals from 3 to 12 weeks post-challenge.</td></tr>
<tr><td>Results</td><td>A cat was considered affected if FeLV antigenemia (detected by p27 in serum) was present for 3 consecutive weeks or on 5 or more occasions, consecutive or not, between the 3rd and 12th week post-challenge.

Summary of FeLV antigenemia results by group:
<table><tr><td>Group</td><td>Positive</td><td>Negative</td></tr><tr><td>Vaccinates</td><td>2</td><td>18</td></tr><tr><td>Controls</td><td>17</td><td>3</td></tr></table>
Raw data are shown below.</td></tr>
<tr><td>USDA Approval Date</td><td>August 18, 2020</td></tr>
</table>

Table 1: FeLV Antigenemia Results Post-Challenge

Animal ID	Treatment Group	Weeks Post-Challenge									
		3	4	5	6	7	8	9	10	11	12
0011	FeLV Vaccinates	-	-	-	-	-	-	-	-	-	-
0045		-	-	-	-	-	-	-	-	-	-
0126		-	-	-	-	-	-	-	-	-	-
0143		-	-	-	-	-	-	-	-	-	-
0215		+	-	-	-	-	-	-	-	-	-
0274		-	-	-	-	-	-	-	-	-	-
0304		-	-	-	-	-	-	-	-	-	-
0410		+	+	+	+	+	+	+	+	+	+
0533		+	+	+	+	+	+	+	+	+	+
0606		-	-	-	-	-	-	-	-	-	-
0631		-	-	-	-	-	-	-	-	-	-
0682		-	-	-	-	-	-	-	-	-	-
0703		-	-	-	-	-	-	-	-	-	-
0819		-	-	-	-	-	-	-	-	-	-
0852		+	-	-	-	-	-	-	-	-	-
0975		-	-	-	-	-	-	-	-	-	-
1025		-	-	-	-	-	-	-	-	-	-
9432		+	-	-	-	-	-	-	-	-	-
9718		-	-	-	-	-	-	-	-	-	-
9858		-	-	-	-	-	-	-	-	-	-
0029	Non-Vaccinated Controls	+	+	+	+	+	+	+	+	+	+
0062		+	+	+	+	+	+	+	+	+	+
0100		+	+	+	+	+	+	+	+	+	+
0151		+	+	+	+	+	-	+	-	-	-
0232		+	+	+	+	+	+	+	-	-	-
0266		+	+	-	+	+	+	+	+	+	+
0339		-	-	-	-	-	-	-	-	-	-
0444		+	+	+	+	+	+	+	+	+	+
0542		+	+	+	+	+	+	+	+	+	+
0584		+	+	+	+	+	+	+	+	+	+
0614		+	-	-	-	-	-	-	-	-	-
0657		+	+	+	+	+	+	+	+	+	+
0712		+	+	+	+	+	+	+	+	+	+
0797		+	+	+	+	+	+	+	+	+	+
0835		+	+	+	+	+	+	+	+	+	+
0959		+	+	+	+	+	+	+	+	+	+
1042		+	+	-	-	-	-	-	-	-	-
9424		+	+	+	+	+	+	+	+	+	+
9688		+	+	+	+	+	+	+	+	+	+
9815		+	+	+	+	+	+	+	+	+	+

\+ positive for FeLV antigen
\- negative for FeLV antigen

<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 in cats under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses administered subcutaneously approximately 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>837 cats represented 7 sites in four geographic locations.
378 cats were 8 weeks of age, 63 cats ranged in age from 9 weeks to 11 months, and 396 cats ranged in age from 1 year to 16 years.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Cats were observed daily for any adverse events from first vaccination through 14 days post-booster vaccination</td></tr>
<tr><td>Results</td><td><u>Summary of Adverse Events:</u>

<table>
<tr><th>VeDDRA Code for Adverse Events Related to the Test Vaccine</th><th>Number of Adverse Events in 1,657 doses</th></tr>
<tr><td>Lethargy</td><td>15 (0.9%)</td></tr>
<tr><td>Injection site pain*</td><td>18 (1.1%)</td></tr>
<tr><td>Emesis (vomiting)</td><td>8 (0.5%)</td></tr>
<tr><td>Anorexia (inappetence)</td><td>3 (0.2%)</td></tr>
<tr><td>General Pain*</td><td>1 (0.1%)</td></tr>
<tr><td>Total</td><td>45 (2.7%)</td></tr>
</table>
*Resolved within 1-3 days

<table>
<tr><th>Vaccination Location</th><th>Total number of doses administered per location</th><th>Local Adverse Event Reaction</th><th>Systemic Adverse Event Reaction</th><th>Total</th></tr>
<tr><td>Hind Leg (Flank)</td><td>1,167</td><td>7</td><td>24</td><td>31</td></tr>
<tr><td>Suprascapular</td><td>489</td><td>11</td><td>3</td><td>14</td></tr>
<tr><td>Other (forelimb)</td><td>1</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Total</td><td>1,657</td><td>18</td><td>27</td><td>45</td></tr>
</table>
</td></tr>
</table>

	VeDDRA Code for Adverse Events Not Related to the Test Vaccine* / **Number of Adverse Events in 1,657 doses**
	Emesis: 26 (1.6%)
	Diarrhea: 12 (0.7%)
	Injection site pain: 9 (0.5%)
	Lethargy: 9 (0.5%)
	Anorexia: 6 (0.4%)
	Behavioral disorder NOS: 4 (0.2%)
	Inappropriate urination: 3 (0.2%)
	Sneezing: 3 (0.2%)
	Cough: 2 (0.1%)
	Encephalitis: 2 (0.1%)
	Epiphora: 2 (0.1%)
	Palpebral edema: 2 (0.1%)
	Trauma NOS: 2 (0.1%)
	Urinary tract obstruction: 2 (0.1%)
	Abnormal behavior: 1 (0.1%)
	Acute (interstitial) pneumonia: 1 (0.1%)
	Dyspnea: 1 (0.1%)
	Dysuria: 1 (0.1%)
	Ear canal disorder: 1 (0.1%)
	Found Dead: 1 (0.1%)
	Gastroenteritis: 1 (0.1%)
	Hyperactivity: 1 (0.1%)
	Hypotension: 1 (0.1%)
	Lameness: 1 (0.1%)
	Localized pain NOS: 1 (0.1%)
	Ocular discharge: 1 (0.1%)
	Other abnormal test results NOS: 1 (0.1%)
	Polydipsia: 1 (0.1%)
	Polyuria/ pollakiuria: 1 (0.1%)
	Pregnancy: 1 (0.1%)
	Regurgitation: 1 (0.1%)
	Renal disorder NOS: 1 (0.1%)
	Systemic disorder NOS: 1 (0.1%)
	Weight gain: 1 (0.1%)
	Weight loss: 1 (0.1%)
	Total: 105 (6.3%)
	*As affirmed by licensee
USDA Approval Date	August 7, 2024