



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1555.R4
True Name	Feline Leukemia Vaccine, Live Canarypox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

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	Feline Leukemia
Study Purpose	To demonstrate efficacy against Feline Leukemia (FeLV) Virus
Product Administration	2 doses subcutaneously, 21 days apart
Study Animals	A total of 43 cats between 57 and 63 days of age at first vaccination. Vaccinates: 21 Controls: 22
Challenge Description	All cats were challenged 3 weeks after second vaccination with FeLV Virus
Interval observed after challenge	Blood samples were collected approximately 3 weeks post-challenge and at weekly intervals for up to 12 consecutive weeks and the sera tested for FeLV antigenemia (p27).
Results	A cat was considered affected when it tested FeLV p27 positive for 3 consecutive weeks or 5 non-consecutive weeks. Raw data on attached sheet.
USDA Approval Date	March 24, 2010

Incidence of FeLV Antigenemia by group, ID and Day

		Day of study														
		6	42	62	69	76	83	90	97	104	111	118	125	132	139	146
Group	id															
Control	AFD1	0	0	1	1	1	0	1	1	1	1	1	0	1	1	0
	AFD2	0	0	1	1	1	0	1	1	1	1	1	1	1	1	1
	AFD6	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	JGH61	0	0	1	1	1	1	1	1	1	1	0	0	0	0	0
	JHB1	0	0	1	1	1	1	1	1	1	1	1	0	1	1	1
	JHD1	0	0	1	1	1	1	1	1	1	1	1	1	0	0	0
	JHD4	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	JHE1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHE4	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHE5	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHG1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHG3	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHH1	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0
	JHH2	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
	JHH3	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
	KHL3	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	KHM5	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	KHM8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	QHC2	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	QHC3	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
QHC4	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
QHC6	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
Vaccinates	id															
	AFD3	0	0	1	1	1	0	1	1	1	1	1	1	1	1	1
	AFD4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHD2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHD5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHD6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHE2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHE3	0	0	1	1	1	1	1	1	1	1	1	0	0	1	1
	JHF4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHG2	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	JHG4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHG7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHH4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	JHH6	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	KHL1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
	KHL2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	KHM1	0	0	1	1	1	1	1	1	1	0	0	0	0	0	0
	KHM4	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	KHM6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	QHC1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
QHC5	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
QHC8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Note: 1=Positive, 0=Negative, Challenge occurred on Days 42 and 43.

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Animals received two doses subcutaneously, approximately 3-4 weeks apart.
Study Animals	<p>A total of 704 cats: ≤8 weeks of age: 262* >8 weeks of age: 442</p> <p>*Two hundred and forty (240) minimum age cats received concurrent vaccination with a commercial vaccine containing core antigens.</p>
Challenge Description	Not applicable
Interval observed after challenge	Observed by veterinarian for 1 hour for any immediate reactions and at least once within 7 days for systemic or local reactions. Owners observed the cats daily for 14 days following vaccination and recorded abnormalities. Any injection site reactions were monitored every 7 days until resolution.
Results	<p>704 cats were vaccinated; 5 owners did not present their cats for a second dose of vaccine.</p> <p>Most adverse events resolved within 48-72 hours without treatment. The same event may have been reported by both the owner and veterinarian.</p> <p>Data on attached page</p>
USDA Approval Date	December 6, 2011

Table 1: Veterinarian-Reported Non-Severe Adverse Events. Cats may be counted in more than one clinical sign category.

Clinical sign classification	Number of events in 1398 doses
Diarrhea	1
Vomiting	1
Anorexia	2
Injection site stinging	51
Injection site swelling	1
Depression	1
Tenderness at injection site	1
Swollen lymph node ^a	1

^a Attributed by licensee to trauma.

Table 2: Veterinarian-Reported Severe Systemic Events. Cats may be counted in more than one clinical sign category.

Clinical sign classification	Number of events in 1398 doses
Gastrointestinal disorders	7 ^a
Cardiovascular disorders	1 ^b
Blood and lymphatic system-Hemolytic anemia	1 ^b
Seizure	1 ^b
Death	5 ^c

^aFive of 7 events are affirmed by licensee to have cause other than vaccination

^bAffirmed by licensee to have cause other than vaccination

^c Four of 5 events are affirmed by licensee to have cause other than vaccination. In the remaining event the cause of death could not be determined due to condition of animal at post-mortem exam. These cats received only one dose of vaccine.

Table 3: Owner-Reported Observations. The same event could be reported by both the owner and veterinarian.

Clinical sign classification	Number of events in 700 reports^a
# cats with no owner observations	592
Anorexia	9
Depression	26
Diarrhea	31
Facial edema	1
Fever	1
Hiding	3
Inappetence	16
Increased bowel movements	1
Increased grooming at injection site.	1
Injection site pain	1
Injection site swelling ^b	5
Irritability	2
Lethargy	19
Limping	3
Listless	2
Malaise	3
Other ^c	11
Pain at injection site	1
Pain on palpation	1
Painful	2
Sneezing	4
Soft stool	1
Tiredness	14
Vocalization	2
Vomiting	27
Warm to touch	1

^a Adverse events are only listed once per cat, even if they were observed after both vaccinations or on more than one day post-vaccination. Cats may be counted in more than one clinical sign category.

^b Swellings resolved within 4 days.

^c Includes dragged toilet paper, drinking a lot, eating grass, infected eyes, limping foot of blood test, nasal discharge, paw pad irritation, roundworms, surgery-found gastric ulcers, upper respiratory infection, urinated outside litter box.