Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	3415.20
True Name	Canine Parvovirus Monoclonal Antibody
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Elanco US, Inc. - Elanco US Inc.
Date of Compilation Summary	April 25, 2023

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	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	One dose, 0.2ml/kg of bodyweight, administered by intravenous route (IV). 6 of the 147 dogs observed were underdosed (sub-potent dose).
Study Animals	147 dogs, of which 62 were ≤ 8 weeks of age.
Challenge Description	Not applicable
Interval observed after challenge	All dogs were observed for 14 ± 2 days post vaccination.
Results	Client-owned dogs were enrolled of various breeds, ranging from 6 weeks of age to 15 years and weighing between 0.6 - 59.2 kg (1.3 – 130 lbs), and located in nine separate sites. **Adverse Reactions** Table 1. Injection Site Reactions IV Route

Injection Site Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction after Intravenous Administration (n=147)**
Erythema	3 (2%)
Inflammation	2 (1%)
Edema	1 (<1%)
Pain	2 (1%)
Total No. of Dogs Affected	6 (4%) *

*Some dogs displayed multiple injection site reactions when affected.

Table 2. Systemic Adverse Reactions IV Route

Adverse Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction after Intravenous Administration (n=147)**
Diarrhea	2 (1%)
Nausea	0
Emesis	0
Anorexia	0
Lethargy	0
Pruritus	1 (<1%)
Total No. of Dogs Affected	3 (2%)

No anaphylactic reactions or clinical presentations consistent with anaphylaxis were reported by the clinical investigators.

Adverse Events

Table 3. Adverse Events Exhibited after IV Administration

Adverse Events VeDDRA Code	**No. of Dogs Exhibiting Adverse Event after Intravenous Administration (n=147)**	**No. of Dogs of Minimum age ≤ 8 Weeks of Age Exhibiting Adverse Event (n=62)**	**No. of Dogs > 8 Weeks of Age Exhibiting Adverse Event (n=85)**	**No. of Dogs Exhibiting Adverse Event, but Underdosed (n=6)** (this column values are already included in values to left)

	Abdominal cavity hernia	2 (1%)	2 (3%)	0	0
	Abnormal behavior	1 (<1%)	0	1 (1%)	0
	Allergic oedema	1 (<1%)	0	1 (1%)	0
	Anemia NOS	0	0	0	0
	Anorexia	3 (2%)	0	3 (4%)	0
	Anxiety disorder	0	0	0	0
	Ataxia	0	0	0	0
	Bacterial skin infection	0	0	0	0
	Bone and joint disorder NOS	0	0	0	0
	Bullous disorder	0	0	0	0
	Congested mucous membrane	1 (<1%)	0	1 (1%)	0
	Convulsion	1 (<1%)	0	1 (1%)	0
	Cough	2 (1%)	0	2 (2%)	0
	Cystitis	0	0	0	0
	Death**	2 (1%)	2 (3%)	0	0
	Dehydration	2 (1%)	2 (3%)	0	0
	Desquamation	0	0	0	0
	Diarrhea	12 (8%)	2 (3%)	10 (12%)	2
	Digestive tract disorder NOS	1 (<1%)	0	1 (1%)	0
	Dyspnea	1 (<1%)	1 (2%)	0	0
	Emesis	2 (1%)	1 (2%)	1 (1%)	0
	Erythema	0	0	0	0
	Flatulence, bloating and distension	0	0	0	0
	Hemorrhagic diarrhea	0	0	0	0
	Hypersalivation	0	0	0	0
	Hypothermia	1 (<1%)	1 (2%)	0	0
	Impaired consciousness	0	0	0	0
	Increased blood urea nitrogen (BUN) or creatinine	1 (<1%)	0	1 (1%)	0
	Injection site erythema	3 (2%)	0	3 (4%)	0
	Injection site inflammation	2 (1%)	0	2 (2%)	0
	Injection site edema	1 (<1%)	0	1 (1%)	0
	Injection site pain	3 (2%)	1 (2%)	2 (2%)	0
	Lethargy	4 (3%)	1 (2%)	3 (4%)	0
	Murmur	0	0	0	0
	Nausea	0	0	0	0
	Nystagmus	0	0	0	0
	Pale mucous membrane	1 (<1%)	1 (2%)	0	0
	Periorbital edema	1 (<1%)	0	1 (1%)	0
	Pruritus	2 (1%)	0	2 (2%)	0
	Recumbency	1 (<1%)	1 (2%)	0	0
	Respiratory tract disorder NOS	12 (8%)	11 (18%)	1 (1%)	3
	Skin lesion NOS	1 (8%)	1 (2%)	0	1
	Sneezing	1 (<1%)	0	1 (1%)	0
	Tachypnoea	2 (1%)	0	2 (2%)	0
	Weight loss	1 (<1%)	0	1 (1%)	0

	<table><tr><td>Total No. of Dogs Exhibiting Adverse Event(s)*</td><td>37 (25%)</td><td>16 (26%)</td><td>21 (25%)</td><td>4</td></tr></table> Table 3. Adverse Events include the adverse reactions listed in Table 1 and 2. Percentage based on actual instance of AE in population of dogs (n=) with an AE. *Some dogs displayed multiple adverse events when affected. **Necropsy deemed deaths unlikely to be related to vaccination by respective study investigator.
USDA Approval Date	March 13, 2023

Study Type	Supplemental Study Information
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	One dose, 0.2ml/kg of bodyweight, administered by subcutaneous route (SC). 19 of the 244 dogs observed were underdosed (sub-potent dose).
Study Animals	244 dogs, of which 161 were ≤ 8 weeks of age.
Challenge Description	Not applicable
	All dogs were observed for 14 ± 2 days post vaccination.
Results	Client-owned dogs were enrolled of various breeds.

Adverse Reactions

Table 1. Injection Site Reactions SC Route

Injection Site Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction after Subcutaneous Administration (n=244)**
Erythema	0
Inflammation	1 (<1%)
Edema	0
Pain	2 (<1%)
Total No. of Dogs Affected	3 (1%)

Table 2. Systemic Adverse Reactions SC Route

Adverse Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction after Subcutaneous Administration (n=244)**
Diarrhea	8 (3%)
Nausea	1 (<1%)
Emesis	2 (<1%)
Anorexia	1 (<1%)
Lethargy	1 (<1%)
Pruritus	0
Total No. of Dogs Affected	10 (4%) *

*Some dogs displayed multiple adverse reactions when affected.

No anaphylactic reactions or clinical presentations consistent with anaphylaxis were reported by the clinical investigators.

Adverse Events

Table 3. Adverse Events Exhibited after Subcutaneous Administration

Adverse Events VeDDRA Code	**No. of Dogs Exhibiting Adverse Event after Subcutaneous Administration (n=244)**	**No. of Dogs of Minimum age ≤ 8 Weeks of Age Exhibiting Adverse Event (n=161)**	**No. of Dogs > 8 Weeks of Age Exhibiting Adverse Event (n=83)**	**No. of Dogs Exhibiting Adverse Event, but Underdosed (n=19)** (this column values are already included in values to left)

	Abdominal cavity hernia	0	0	0	0
	Abnormal behavior	0	0	0	0
	Allergic oedema	0	0	0	0
	Anemia NOS	1 (<1%)	1 (<1%)	0	0
	Anorexia	5 (2%)	1 (<1%)	4 (5%)	0
	Anxiety disorder	1 (<1%)	0	1 (1%)	0
	Ataxia	2 (<1%)	2 (1%)	0	0
	Bacterial skin infection	2 (<1%)	2 (1%)	0	2
	Bone and joint disorder NOS	2 (<1%)	2 (1%)	0	2
	Bullous disorder	1 (<1%)	0	1 (1%)	0
	Congested mucous membrane	0	0	0	0
	Convulsion	0	0	0	0
	Cough	1 (<1%)	0	1 (1%)	0
	Cystitis	1 (<1%)	0	1 (1%)	0
	Death	2 (1%)	2 (1%)	0	0
	Dehydration	0	0	0	0
	Desquamation	2 (<1%)	2 (1%)	0	0
	Diarrhea	20 (8%)	14 (9%)	6 (7%)	0
	Digestive tract disorder NOS	1 (<1%)	0	1 (1%)	0
	Dyspnea	0	0	0	0
	Emesis	7 (3%)	1 (<1%)	6 (7%)	0
	Erythema	1 (<1%)	0	1 (1%)	0
	Flatulence, bloating and distension	1 (<1%)	0	1 (1%)	0
	Hemorrhagic diarrhea	4 (2%)	4 (3%)	0	0
	Hypersalivation	1 (<1%)	0	1 (1%)	0
	Hypothermia	0	0	0	0
	Impaired consciousness	3 (<1%)	3 (2%)	0	1
	Increased blood urea nitrogen (BUN) or creatinine	0	0	0	0
	Injection site erythema	0	0	0	0
	Injection site inflammation	1 (<1%)	0	1 (1%)	0
	Injection site edema	0	0	0	0
	Injection site pain	2 (<1%)	2 (1%)	0	0
	Lethargy	7 (3%)	4 (3%)	3 (4%)	0
	Murmur	1 (<1%)	0	1 (1%)	0
	Nausea	1 (<1%)	1 (<1%)	0	0
	Nystagmus	1 (<1%)	1 (<1%)	0	0
	Pale mucous membrane	1 (<1%)	1 (<1%)	0	0
	Periorbital edema	0	0	0	0
	Pruritus	0	0	0	0
	Recumbency	0	0	0	0
	Respiratory tract disorder NOS	16 (7%)	16 (10%)	0	3
	Skin lesion NOS	0	0	0	0
	Sneezing	1 (<1%)	0	1 (1%)	0
	Tachypnoea	0	0	0	0
	Weight loss	0	0	0	0

Total No. of Dogs Exhibiting Adverse Event(s)*	55 (23%)	40 (25%)	15 (18%)	6

Table 3. Adverse Events include the adverse reactions listed in Table 1 and 2. Percentage based on actual instance of AE in population of dogs (n=) with an AE.

*Some dogs displayed multiple adverse events when affected.

**Necropsy deemed deaths unlikely to be related to vaccination by respective study investigator.