Summary of Studies Supporting USDA Product Licensure

Establishment Name	Medgene Labs
USDA Vet Biologics Establishment Number	474
Product Code	9PP0.R2
True Name	Prescription Product, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 03, 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	Demonstration of safety in cattle under typical field conditions.
Product Administration	One dose administered subcutaneously, followed by a second dose 3 weeks later. The vaccine contained genes from Coronavirus S1, Bovine Rotavirus Type A VP4, and two Bovine Influenza D virus HE antigens.
Study Animals	700 cattle, 521 of which were 3 days of age or younger. The study included three distinct geographical locations.
Challenge Description	Not applicable
Interval observed after challenge	Cattle were observed daily, and injection site palpations were conducted one day after each injection and 14 days after the second injection.
Results	Table 1, Size of injection site reactions:

Vaccination	< 1.5 cm	1.5 – 5 cm
1st	91	52
2nd	59	112

Table 2, Duration (days) of injection site reactions:

Vaccination	Min	Q1	Median	Q3	Max
1st	4.0	20.0	20.0	20.0	48.0
2nd	1.0	13.0	13.0	13.0	35.0

Table 3, Percentages of cattle with specific clinical observations:

Adverse Event	Number Affected	Percent Affected
Injection site edema	288	32.6
Diarrhea	158	22.6
Pneumonia	91	13.0
Mortality*	11	1.6
Anorexia	7	1.0
Injection site reaction	2	0.29
Lethargy	2	0.29
Hyperthermia	1	0.14

*Mortality due to causes other than vaccination as affirmed by licensee

Table 4, Adverse events by site:

Site	Number Vaccinated	Number Affected	Percent
1	230	6	2.6
2	230	16	7.0
3	240	208	86.7

Table 5, Injection site adverse events by age:

Age	Number Vaccinated	Number Affected	Percent
≤ 3 days	521	217	41.7
> 3 days	179	13	7.3

USDA Approval Date	August 1, 2022

Study Type	Safety
Pertaining to	Prescription Platform Product
Study Purpose	Safety
Product Administration	Intramuscular
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	This product was qualified as a prescription production platform based on demonstrated safety as shown in the Product Summary for Establishment 474, Code 19A5.RA. As a prescription platform product, the manufacturer may update the gene insert in this vaccine under expedited procedures to respond to emerging needs per Veterinary Services Memorandum 800.214. Study data to support these updates were evaluated by USDA-APHIS and found acceptable based on regulations and policies at the time of approval. Additional safety studies may not have been required for these updates. An identifier for the gene sequence found in a given serial (numbered batch) of vaccine is listed on the product labeling.
USDA Approval Date	November 8, 2021