



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Medgene Labs
USDA Vet Biologics Establishment Number	474
Product Code	9PP0.R0
True Name	Prescription Product, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	September 10, 2021

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	Prescription Platform Product
Study Purpose	Safety
Product Administration	Intramuscular
Study Animals	Swine
Results	<p>This product was qualified as a prescription production platform based on demonstrated safety as shown in the Product Summary of Establishment 474, Code 19A5.R9.</p> <p>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.</p> <p>An identifier for the gene sequence found in a given serial (numbered batch) of vaccine is listed on the product labeling.</p>
USDA Approval Date	June 09, 2020