

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	303A
Product Code	1K11.00
True Name	Arthrobacter Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Renogen - Elanco US, Inc.
Date of Compilation Summary	June 25, 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.

303A 1K11.00 Page 1 of 3

Study Type	Efficacy
Pertaining to	Renibacterium salmoninarum
Study Purpose	To demonstrate effectiveness against Bacterial Kidney Disease
_	caused by Renibacterium salmoninarum.
Product Administration	
Study Animals	Atlantic salmon and Chinook salmon
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	December 1, 2000

303A 1K11.00 Page 2 of 3

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under laboratory conditions
Product Administration	
Study Animals	Atlantic salmon
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	December 1, 2000

303A 1K11.00 Page 3 of 3