

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	17E1.20
True Name	Hemorrhagic Enteritis Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health Oralvax HE - Intervet Veterinaria Chile Ltda Oralvax HE - Merck Animal Health Oralvax HE - No distributor specified
Date of Compilation Summary	October 19, 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.

165A 17E1.20 Page 1 of 3

Study Type	Efficacy
Pertaining to	Hemorrhagic Enteritis Vaccine, Live Virus
Study Purpose	To demonstrate effectiveness against Hemorrhagic Enteritis
	Virus
<b>Product Administration</b>	Drinking water
Study Animals	Turkeys
<b>Challenge Description</b>	
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 11, 1988

165A 17E1.20 Page 2 of 3

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under typical field conditions
<b>Product Administration</b>	Drinking water
Study Animals	Turkeys
<b>Challenge Description</b>	
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. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	April 12, 1989

165A 17E1.20 Page 3 of 3