Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	15B9.20
True Name	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Feline 1-HCP+FeLV - Merck Animal Health Nobivac Feline 1-HCP+FeLV - No distributor specified Nobivac HCP+FeLV - No distributor specified
Date of Compilation Summary	April 10, 2019

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	Efficacy
Pertaining to	Feline Calici Virus (FCV)
Study Purpose	To demonstrate efficacy against FCV.
Product Administration	
Study Animals	Feline
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 for 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.
USDA Approval Date	August 19, 1999

Study Type	Efficacy
Pertaining to	Feline Leukemia Virus (FeLV)
Study Purpose	To demonstrate efficacy against FeLV
Product Administration	
Study Animals	Feline
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. 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.
USDA Approval Date	August 19, 1999

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Feline Leukemia Virus (FeLV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy against FeLV two years after vaccination</td></tr>
<tr><td>Product Administration</td><td>Two doses administered by the subcutaneous route 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>23 cats, 52 to 58 days of age at time of 1st vaccination; 12 vaccinates and 11 controls</td></tr>
<tr><td>Challenge Description</td><td>Cats were immunosuppressed then challenged with FeLV two years after the 2nd vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Clinical signs were observed daily, and blood samples were collected at weekly intervals from 3 to 12 weeks post-challenge.</td></tr>
<tr><td>Results</td><td>Viremia - A positive animal was defined by the presence of FeLV during 3 or more consecutive weeks or a total of 5 positive results during the post-challenge collection period.

<table>
<tr><th>Group</th><th># of Animals</th><th># Positive for Viremia</th></tr>
<tr><td>Vaccinates</td><td>12</td><td>2 (17%)</td></tr>
<tr><td>Controls</td><td>11</td><td>11 (100%)</td></tr>
</table>

Raw data shown on attached pages. Treatment Group 1 is vaccinates and Treatment Group 2 is controls.</td></tr>
<tr><td>USDA Approval Date</td><td>January 25, 2010</td></tr>
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FeLV p27 IDEXX ELISA Results (Post-Challenge Phase)

Treatment Group	Animal ID	6 months prior to challenge Day -177	Day -2 prior to challenge	Weeks Post Challenge									
				3	4	5	6	7	8	9	10	11	12
1	JAA1	0.039	0.039	0.050	0.042	0.040	0.042	0.039	0.039	0.044	0.043	0.039	0.035
1	JAB1	0.038	0.037	0.102	0.043	0.053	0.045	0.039	0.039	0.043	0.045	0.040	0.043
1	JAB2	0.040	0.037	0.045	0.043	0.038	0.039	0.040	0.043	0.045	0.045	0.039	0.044
1	JAB5	0.039	0.037	0.050	0.042	0.043	0.042	0.039	0.040	0.044	0.045	0.044	0.042
1	JAC5	0.040	0.037	**0.238**	**0.409**	**0.799**	**0.759**	**0.944**	**1.242**	**1.059**	**1.404**	**1.039**	**1.211**
1	JAD3	0.038	0.039	0.040	0.040	0.042	0.042	0.040	0.037	0.042	0.043	0.042	0.043
1	JAE5	0.053	0.038	0.040	0.040	0.037	0.042	0.039	0.037	0.040	0.044	0.043	0.043
1	JAH3	0.036	0.039	0.040	0.038	0.037	0.040	0.040	0.037	0.040	0.043	0.061	0.043
1	JAI4	0.036	0.038	0.041	0.042	0.039	0.040	0.041	0.038	0.040	0.042	0.043	0.042
1	JAI5	0.037	0.039	0.041	0.039	0.039	0.043	0.041	0.038	0.040	0.044	0.046	0.041
1	JAM2	0.038	0.038	0.126	0.106	0.040	0.043	0.042	0.040	0.044	0.043	0.042	0.043
1	JAM3	0.037	0.037	**0.874**	**1.078**	**0.883**	**0.472**	**0.752**	**0.874**	**1.028**	**1.692**	**0.971**	**0.633**
2	JAA2	0.038	0.039	**0.605**	**0.453**	**0.806**	**0.303**	**0.542**	**0.552**	**0.716**	**1.196**	**1.027**	**0.686**
2	JAB4	0.040	0.036	**0.405**	**0.563**	**0.955**	**1.286**	**1.258**	*euthanized*				
2	JAC1	0.038	0.037	**1.187**	**1.061**	**2.002**	**1.161**	**1.844**	**0.968**	**1.433**	**1.706**	**1.225**	**1.005**
2	JAC4	0.040	0.037	**0.949**	**1.036**	**1.141**	**0.971**	**1.561**	**0.880**	**1.376**	**1.531**	**0.949**	**1.209**
2	JAC6	0.038	0.037	**1.252**	**1.222**	**1.555**	**0.872**	**0.793**	**0.542**	**0.751**	**1.128**	**0.968**	**0.865**
2	JAC7	0.036	0.037	**1.023**	**0.674**	**1.417**	**0.821**	**1.102**	**0.947**	**1.287**	**1.450**	**1.007**	**0.884**
2	JAE1	0.037	0.039	**0.501**	**0.405**	**0.771**	**0.405**	**0.758**	**0.769**	**0.815**	**1.343**	**0.893**	**0.877**
2	JAI1	0.037	0.038	**0.634**	**0.653**	**0.884**	**0.854**	**0.873**	**0.948**	**0.581**	**1.440**	**1.132**	**1.070**
2	JAK3	0.036	0.039	**0.439**	**0.745**	**0.850**	**0.792**	**0.847**	**0.868**	**0.843**	**1.418**	**1.036**	**0.537**
2	JAM6	0.037	0.038	**0.441**	**1.363**	**1.413**	**0.794**	**0.723**	**1.072**	**0.732**	**2.029**	**1.448**	**0.549**
2	JAN3	0.038	0.039	**0.496**	**0.426**	**1.045**	**1.124**	**1.322**	**1.125**	**1.140**	**1.353**	**1.178**	**1.058**

Optical d equal to or greater than 0.200 are considered positive for FeLV p27. Bolded and underlined numbers indicate a positive result.

Study Type	Efficacy
Pertaining to	Feline Rhinotracheitis Virus (FRV)
Study Purpose	To demonstrate efficacy against FRV.
Product Administration	
Study Animals	Feline
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 for 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.
USDA Approval Date	August 19, 1999

Study Type	Efficacy
Pertaining to	Feline Panleukopenia Virus (FPL)
Study Purpose	To demonstrate efficacy against FPL.
Product Administration	
Study Animals	Feline
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 for 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.
USDA Approval Date	August 19, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	
Study Animals	Feline
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 for 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.
USDA Approval Date	April 7, 1992