



Summary of Studies Supporting USDA Product Licensure

| | |
|---|--|
| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 16D1.21 |
| True Name | Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Solo-Jec Feline 3 - No distributor specified |
| Date of Compilation Summary | October 21, 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 Calicivirus (FCV) |
| Study Purpose | To demonstrate effectiveness against respiratory disease due to Feline Calicivirus |
| Product Administration | Two doses administered 21 days apart subcutaneously (SC) |
| Study Animals | Thirty three (33) cats, 8 weeks of age. Cat were randomized into one vaccinated group of 23 cats and one group of 10 non-vaccinated controls. |
| Challenge Description | 31 days post second vaccination all cats were challenged with FCV. |
| Interval observed after challenge | Rectal temperatures and clinical signs were observed daily for 14 days post challenge. |
| Results | <p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.314(c)(3)</p> <p>A significant difference in clinical signs was observed between vaccinates and controls using a scoring system approved by APHIS.</p> <p>Requirements of 113.314(c)(3) were met.</p> <p>See the next page for data.</p> |
| USDA Approval Date | November 4, 1998 |

FCV Post challenge Daily Clinical Signs

| Cat ID | Vaccinates | | | | | | | | | | | | | | |
|--------|------------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 2 | | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 3 | | | | | | 1 | 1 | 1 | 1 | 1 | | | | | |
| 4 | | | | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 5 | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | |
| 7 | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 1 |
| 8 | | | | | | | 1 | 1 | | | | | | | |
| 9 | | | | | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 10 | | | | | | 3,2 | 3,2 | 3,2 | 3,2 | 3,2 | 3 | 3 | 3 | 1 | |
| 11 | | | | | 1,2,5 | 1,2,5 | 1,2,5 | 1,2,5 | 1,2,5 | 1,2,5 | 2,5 | 2,5 | 1,5 | 1 | 1 |
| 12 | | | | | | | | | | | | | | | |
| 13 | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 14 | | | | | 5 | | | | 3,6 | 1 | | | | | |
| 15 | | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 16 | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 17 | | | | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 18 | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 19 | | | | | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
| 20 | | | | | | | | | | | | | | | |
| 21 | | | | | | | | | | | | | | | |
| 22 | | | | 5 | 5 | 5 | 5 | | | | | | | | |
| 23 | | | | | 2 | 1,2 | 1,2 | 1,2 | 1,2 | 1,2 | 2 | 2 | 1 | 1 | 1 |

No entry=no signs noted

9 - snuffing

5- External Non-bleeding ulcer(s)

1- One oral ulcer <4mm

10 - coughing

6- External bleeding ulcer(s)

2- One oral ulcer >4mm

11- mouth breathing

7- Anorexia

3- Multiple oral ulcers <4mm

12 - Depression

8- Dehydration

4- Multiple oral ulcers >4mm

DPC – days post-challenge

FCV Post challenge Daily Clinical Signs

| Non-Vaccinated Controls | | | | | | | | | | | | | | | |
|-------------------------|------|------|------|------|-------|-------|-------|------|------|------|-------|-------|-------|-------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | | | 5 | 5 | 5 | 5 | 5 | 5 | | | | |
| 2 | | | 1 | 1 | 1,2,6 | 1,2,6 | 1,2,6 | 2,6 | 2,6 | 2,6 | 2,6 | 2,6 | 2,6 | 2,6 | 2,6 |
| 3 | | | | | 4 | 4 | 4 | 4 | 4 | 4 | 3 | | | | |
| 4 | | | | 1 | 2 | 2 | 2 | 1,2 | 1,2 | 1,2 | 1,2 | 3,2 | 3,2 | 3,2 | 2 |
| 5 | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 6 | | | | 3,2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 7 | | | | | | | | | | 1 | 1 | 1 | 1 | 1 | 1 |
| 8 | | | | | | 4,6 | 4,6 | 4,6 | 4,6 | 4,6 | 4,6 | 4,6 | 1,2,5 | 1,2,5 | 1,2,5 |
| 9 | | | | | 2 | 2 | 2 | 1,2 | 1,2 | 1,2 | 2 | 2 | 2 | 2 | 2 |
| 10 | | | | | | 3 | 3 | 4 | 4 | 4 | 4 | 1,2 | 1,2 | 1,2 | 3 |

DPC – days post-challenge

- 1- One oral ulcer <4mm
- 2- One oral ulcer >4mm
- 3- Multiple oral ulcers <4mm
- 4- Multiple oral ulcers >4mm

- 5- External Non-bleeding ulcer(s)
- 6- External bleeding ulcer(s)
- 7- Anorexia
- 8- Dehydration

9 - snuffing

10 - coughing

11- mouth breathing

12 - Depression

No entry=no signs noted

FCV Post challenge Daily Body Temperature (°F)

| Cat ID | Vaccinates | | | | | | | | | | | | | | | | | | | | | | |
|--------|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--|--|--|--|--|--|--|--|
| | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | | | | | | | | |
| 1 | 101.9 | 102.4 | 101.9 | 102.2 | 102.1 | 102.4 | 101.3 | 101.4 | 101.6 | 101.5 | 101.2 | 101.1 | 101.1 | 101.1 | 101.3 | | | | | | | | |
| 2 | 101.7 | 101.6 | 101.9 | 102.1 | 103.1 | 101.4 | 101.8 | 101.0 | 101.8 | 101.4 | 101.7 | 101.4 | 101.7 | 101.3 | 101.8 | | | | | | | | |
| 3 | 101.2 | 102.1 | 101.8 | 102.7 | 101.5 | 101.8 | 101.2 | 101.0 | 101.4 | 101.1 | 101.0 | 101.1 | 101.4 | 101.0 | 101.7 | | | | | | | | |
| 4 | 101.8 | 102.6 | 101.7 | 102.6 | 101.9 | 102.0 | 102.0 | 101.5 | 101.2 | 101.8 | 101.7 | 101.7 | 101.2 | 101.8 | 101.7 | | | | | | | | |
| 5 | 100.8 | 101.0 | 100.8 | 101.6 | 101.5 | 101.4 | 101.4 | 101.9 | 101.7 | 101.5 | 101.1 | 101.3 | 101.1 | 101.4 | 101.4 | | | | | | | | |
| 6 | 101.7 | 102.1 | 101.3 | 101.1 | 101.3 | 101.1 | 101.5 | 101.0 | 101.4 | 101.7 | 101.2 | 101.5 | 101.0 | 101.2 | 101.6 | | | | | | | | |
| 7 | 101.2 | 103.2 | 101.5 | 102.6 | 101.9 | 101.5 | 101.5 | 101.0 | 101.5 | 101.4 | 101.9 | 101.9 | 101.9 | 101.3 | 101.9 | | | | | | | | |
| 8 | 101.6 | 101.7 | 101.6 | 101.9 | 101.7 | 101.9 | 101.5 | 101.7 | 101.5 | 101.5 | 101.5 | 101.6 | 101.2 | 101.5 | 101.0 | | | | | | | | |
| 9 | 101.5 | 102.1 | 101.7 | 101.9 | 102.0 | 101.8 | 101.2 | 101.6 | 101.6 | 101.1 | 101.8 | 101.6 | 101.7 | 101.1 | 101.1 | | | | | | | | |
| 10 | 101.3 | 103.1 | 102.1 | 102.1 | 102.1 | 101.7 | 101.8 | 101.0 | 101.4 | 101.4 | 101.4 | 101.5 | 101.1 | 101.0 | 101.8 | | | | | | | | |
| 11 | 100.3 | 102.2 | 102.1 | 103.0 | 102.9 | 102.1 | 102.0 | 101.0 | 101.5 | 101.6 | 101.9 | 101.4 | 101.0 | 101.0 | 101.2 | | | | | | | | |
| 12 | 102.3 | 103.0 | 102.4 | 101.6 | 101.7 | 103.1 | 101.8 | 102.2 | 101.8 | 101.4 | 101.7 | 101.9 | 101.9 | 101.3 | 101.1 | | | | | | | | |
| 13 | 101.2 | 101.4 | 101.2 | 101.7 | 101.2 | 101.8 | 101.7 | 101.4 | 101.8 | 101.1 | 101.4 | 101.4 | 101.5 | 101.4 | 101.5 | | | | | | | | |
| 14 | 100.4 | 102.3 | 101.8 | 101.2 | 101.7 | 101.9 | 101.5 | 101.3 | 101.8 | 101.9 | 101.1 | 101.1 | 101.7 | 101.6 | 101.5 | | | | | | | | |
| 15 | 101.6 | 102.1 | 102.4 | 102.0 | 101.6 | 101.6 | 101.2 | 101.2 | 102.3 | 101.5 | 101.2 | 101.0 | 101.6 | 101.0 | 101.0 | | | | | | | | |
| 16 | 100.9 | 102.1 | 103.7 | 103.4 | 102.9 | 102.5 | 102.3 | 101.8 | 101.4 | 101.6 | 101.3 | 101.2 | 101.2 | 101.0 | 101.1 | | | | | | | | |
| 17 | 101.5 | 102.8 | 101.8 | 102.4 | 102.6 | 102.1 | 101.1 | 101.8 | 101.6 | 101.9 | 102.0 | 101.9 | 101.4 | 101.4 | 102.0 | | | | | | | | |
| 18 | 101.0 | 102.0 | 101.1 | 103.4 | | 101.1 | 101.0 | 101.0 | 101.1 | 101.2 | 101.2 | 101.3 | 101.7 | 101.3 | 101.6 | | | | | | | | |
| 19 | 100.8 | 102.5 | 101.4 | 101.0 | 102.1 | 101.5 | 101.8 | 101.3 | 101.1 | 101.8 | 101.4 | 101.4 | 101.3 | 101.1 | 101.0 | | | | | | | | |
| 20 | 100.5 | 101.7 | 101.7 | 101.4 | 102.0 | 101.0 | 101.6 | 101.3 | 101.2 | 101.1 | 101.1 | 101.4 | 101.7 | 101.1 | 101.0 | | | | | | | | |
| 21 | 101.9 | 102.4 | 102.0 | 101.8 | 101.8 | 101.9 | 101.1 | 101.5 | 101.8 | 101.8 | 102.0 | 102.1 | 101.1 | 101.2 | 101.6 | | | | | | | | |
| 22 | 100.4 | 101.7 | 102.1 | 102.0 | 102.0 | 101.2 | 101.6 | 101.4 | 102.0 | 101.3 | 101.9 | 101.4 | 101.1 | 101.1 | 101.0 | | | | | | | | |
| 23 | 101.0 | 102.7 | 102.6 | 102.8 | 101.4 | 102.3 | 101.6 | 101.3 | 101.4 | 101.0 | 101.3 | 101.6 | 101.5 | 101.6 | 101.2 | | | | | | | | |

DPC – days post-challenge

FCV Post challenge Daily Body Temperature (°F)

| Non-Vaccinated Controls | | | | | | | | | | | | | | | |
|--------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | 100.3 | 102.1 | 101.7 | 101.5 | 102.1 | 102.4 | 102.4 | 101.7 | 102.0 | 101.0 | 101.4 | 101.0 | 101.0 | 101.6 | 101.3 |
| 2 | 101.0 | 101.7 | 101.4 | 102.2 | 102.9 | 102.1 | 101.6 | 101.3 | 101.5 | 101.3 | 101.1 | 101.4 | 101.4 | 101.5 | 101.1 |
| 3 | 102.0 | 102.8 | 101.9 | 102.3 | 101.8 | 101.3 | 101.2 | 101.3 | 101.4 | 101.7 | 101.9 | 101.4 | 101.0 | 101.6 | 101.2 |
| 4 | 102.7 | 102.7 | 102.4 | 102.8 | 102.8 | 101.5 | 101.2 | 101.8 | 101.3 | 101.2 | 101.1 | 101.7 | 101.6 | 101.2 | 101.4 |
| 5 | 101.7 | 102.1 | 102.1 | 103.6 | 102.3 | 102.7 | 102.1 | 102.2 | 102.0 | 101.1 | 101.2 | 101.1 | 101.6 | 101.0 | 101.7 |
| 6 | 101.0 | 102.0 | 101.4 | 104.0 | 103.0 | 103.1 | 102.7 | 101.0 | 101.0 | 101.3 | 101.0 | 101.0 | 101.0 | 101.3 | 101.7 |
| 7 | 101.1 | 102.6 | 101.3 | 101.4 | 102.0 | 102.3 | 101.4 | 101.3 | 101.1 | 101.6 | 101.5 | 101.6 | 101.8 | 101.9 | 101.2 |
| 8 | 102.0 | 102.5 | 102.1 | 101.6 | 101.1 | 102.4 | 101.6 | 101.7 | 101.7 | 102.1 | 101.2 | 101.5 | 101.6 | 101.3 | 101.6 |
| 9 | 102.1 | 102.2 | 102.0 | 102.4 | 103.2 | 103.2 | 102.1 | 102.3 | 101.6 | 101.6 | 101.5 | 101.7 | 101.2 | 101.1 | 101.0 |
| 10 | 102.7 | 102.4 | 103.7 | 104.6 | 103.9 | 102.9 | 101.3 | 102.5 | 101.9 | 101.8 | 101.7 | 101.1 | 101.2 | 101.2 | 101.3 |

DPC – days post-challenge

| | |
|--|--|
| Study Type | Efficacy |
| Pertaining to | Feline Viral Rhinotracheitis (FVR) |
| Study Purpose | To demonstrate effectiveness against FVR |
| Product Administration | Two doses administered 21 days apart subcutaneously (SC) |
| Study Animals | Forty-two (42) cats, 8 weeks of age. Cats were randomized into two vaccinated groups of 22 and 10 cats, respectively, and one group of 10 non-vaccinated controls. |
| Challenge Description | 21 days post second vaccination all cats were challenged with FVR virus. |
| Interval observed after challenge | Rectal temperatures and clinical signs were observed daily for 14 days post challenge. |
| Results | <p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.315(c)(3)</p> <p>A significant difference in clinical signs was observed between vaccinates and controls using a scoring system approved by APHIS.</p> <p>Requirements of 113.315(c)(3) were met.</p> <p>See the next page for data.</p> |
| USDA Approval Date | July 1, 1999 |

FVR Post challenge Daily Clinical Signs

| Vaccinates - Group 1 | | | | | | | | | | | | | | | |
|----------------------|------|------|------|------|---------|-----------|-----------|---------------|------------|------------------|---------------|---------------|---------------|-----------|--------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | SN | D,DH,DY | DH,NSM,AN | SN,DH,AN | SN,NSM,AN | SN,AN | NSM,AN | SN,OSM,NSM,AN | OSM,NSM,AN | NSM,AN | SN | AN |
| 2 | | D | | D | OSM,NSM | D,DH,NSM | SN,DH,AN | OSM,NSM,AN | OMM,NMM,AN | OSM,NMM,AN | NSM,AN | NSM,AN | | NSM | NMM |
| 3 | | | | | | OSM | | OSM,NSM | OSM,NSM | NSM | NSM | | | | NSM |
| 4 | | | | | | | SN | SN,NSM | NSM | SN,NSM | NSM | SN,NSM | SN,NSM | SN,NSM | NSM |
| 5 | | | | | | | OSM | OSM | OSM | | | OSM,NSM | OSM,NSM | SN,NSM | |
| 6 | | | | | SN | DH | | NSM | | SN | | | | NSM | |
| 7 | | | | SN | | SN,OSM | | NSM | | | SN | NSM | SN,NSM | SN | |
| 8 | | | | | SN,DY | | SN,DY | SN | AN | SN,NSM | NSM | NSM | NSM | | NSM |
| 9 | | | | | | | SN | SN,OSM,NSM | AN | NSM,AN | NSM | NSM | NSM | NSM | NSM |
| 10 | | | | | | | OSM | OSM | OSM,NSM | SN,OSM | OSM,NMM | NSM | | | |
| 11 | | | | | OSM | OSM,NSM | DY | SN | NSM | NSM | NSM | NSM | NSM | SN,NSM | NMM |
| 12 | | | | SN | | OSM | OSM | SN,OSM | NSM | | NSM | NSM | OSM | | |
| 13 | | | | | | | | NSM | | | | | | | |
| 14 | | | | | | | | SN | | | | | | | |
| 15 | | | | | | | OSM | OSM | NSM | SN | NSM | NSM | | SN | |
| 16 | | | | SN | SN | SN,OSM | SN,DY | SN,NSM | | | SN,NSM | NSM | SN,OMM,NSM | SN | |
| 17 | | | | | SN | AN | AN | SN,NSM,AN | AN | | | | | | |
| 18 | | | | | | | | NSM | SN,NSM | NSM | SN | NSM | NSM | | NSM |
| 19 | | | | | | | SN | | | NSM | NSM | | | SN | |
| 20 | | | | | | AN | AN | SN,OSM,NSM,AN | AN | NSM,AN | NSM | NSM | NSM | SN | NSM |
| 21 | | | | | SN,AN | SN,DH,AN | SN,OSM,AN | OSM,NSM,AN | OSM,NMM,AN | SN,DH,OSM,NSM,AN | SN,OSD,NSD,AN | SN,OMM,NMM,AN | SN,OMM,NMM,AN | SN,NSM,AN | NSM,AN |
| 22 | | | | | | | | SN,NSM,AN | NSM,AN | AN | NSM,AN | NSM | | | |

Empty=no signs observed

| Ocular Discharge | Nasal Discharge | SN-Sneezing | CO-Coughing |
|---------------------|---------------------|----------------|-------------------------|
| OSM-Mild serous | NSM - Mild Serous | AN-Anorexia | BR-Open Mouth Breathing |
| OSD-Moderate serous | NSD-Moderate Serous | DH-Dehydration | D-Depression |
| OMM-Mild Mucoid | NMM-Mild Mucoid | DY-Snuffing | |
| OMD-Moderate Mucoid | NMD-Moderate Mucoid | | |

DPC – Days post-challenge

FVR Post challenge Daily Clinical Signs

| Vaccinates - Group 2 | | | | | | | | | | | | | | | |
|----------------------|------|------|------|------|-----------|-----------|--------|---------------|------------|------------|---------|---------|--------|--------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | | SN | | | NSM | SN,NSM | NMM | AN | NSM | SN,NSM | SN,NSM | |
| 2 | | | | SN | SN,CO,OSM | SN,OSM,BR | SN,OSM | SN,OSM,NSM | SN,OSM,NSM | SN,OSM,NSM | SN,OSM | OSM | SN,OSM | | |
| 3 | | | | | OSM | OSM | OSM | OSM | SN,NSM | SN,OSM,NSM | NSM | OSM,NSM | | NSM | |
| 4 | | | | | OSM | | OSM | SN,NSM | | SN,NSM | NSM | | | SN | NMM |
| 5 | | | | | | OSM | NSM | SN | SN,NSM | NSM,AN | SN,OSM | OSM | SN,OSM | SN | |
| 6 | | | | | SN,OSM | | SN,NSM | SN,NSM | NSM | NSM | SN,OSM | SN | NSM | SN | |
| 7 | | | | D | | | | | | | | | | | |
| 8 | | | | SN | SN,OSM | AN | SN | NSM,AN | OSM,NSM,AN | NMM,AN | NMM,AN | NMM,AN | | SN | AN |
| 9 | | | | SN | SN,OSM | SN,OSM | SN | SN,OSM,NSM | NSM | SN | SN,OSM | SN | SN,NSM | SN | |
| 10 | | | | | DY,OSM | | | SN,OSM,NSM,AN | OSM,NMM,AN | SN,NMM | OSM,NSM | NSM | NSM | SN,NSM | NSM |

Non-Vaccinated Controls

| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|--------|------|------|------|------|-------|--------------|-----------|---------------|----------------|---------------|---------------|------------|------------|---------------|--------|
| 1 | | | | | | SN,D,OSM | SN | SN,OSM,NSM | NSM | SN,NSM | | SN,NSM | NSM | | |
| 2 | | | | | | OSM | SN,AN | SN,NSM,AN | OSM,AN | DH,OMM,NMM,AN | SN,OMM,NMM,AN | OMM,NMM,AN | OMM,NMM,AN | SN,OMM,NMM,AN | NSM,AN |
| 3 | | | | | SN | DH,OSM | | NSM,AN | SN,D,DY,OSM,AN | SN,OSM,NSM,AN | OMM,AN | OMM,AN | OSM,AN | SN | AN |
| 4 | | | | | OSM | OSM | OSM | OSM | OSM,NSM,AN | SN,OSM,AN | OSM | OSM | NSM | | |
| 5 | | AN | | | | SN,OSM,AN | OSM | SN,OSM,NSM | NSM,AN | NSM,AN | SN,AN | NSM,AN | NSM,AN | SN,NSM,AN | NSM,AN |
| 6 | | | | | SN,CO | SN,OSM | SN | SN | SN,NSM | NSM | SN,NSM | SN,NSM | SN,NSM | SN,NSM | |
| 7 | | | | | SN | SN | SN,OSM | SN,AN | SN,OSM,AN | SN,NSM,AN | SN,AN | SN | SN | | |
| 8 | | | | | SN | SN,NSM | | SN | DY,NSM | SN,OSM | | | SN | NSM | |
| 9 | | | | | | | | SN,OSM | NSM | OSM | SN,NSM | NSM | NSM | SN,NSM | |
| 10 | | | | | SN,DY | SN,OSM,BR,AN | SN,OSM,AN | SN,OSM,NSM,AN | DY,OSM,NSM,AN | SN,OSM,NSM,AN | OSM,NSM,AN | OSM,NSM,AN | SN | SN | AN |

Empty=no signs observed

| Ocular Discharge | Nasal Discharge | SN-Sneezing | CO-Coughing |
|---------------------|---------------------|----------------|-------------------------|
| OSM-Mild serous | NSM - Mild Serous | AN-Anorexia | BR-Open Mouth Breathing |
| OSD-Moderate serous | NSD-Moderate Serous | DH-Dehydration | D-Depression |
| OMM-Mild Mucoid | NMM-Mild Mucoid | DY-Snuffing | |
| OMD-Moderate Mucoid | NMD-Moderate Mucoid | | |

DPC – Days post-challenge

FVR Post challenge Daily Body Temperature (°F)

| Cat ID | Vaccinates - Group 1 | | | | | | | | | | | | | | | | | | | | | |
|--------|----------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--|--|--|--|--|--|--|
| | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | | | | | | | |
| 1 | 100.4 | 100.0 | 101.1 | 100.0 | 103.4 | 101.6 | 101.2 | 101.1 | 100.3 | 101.4 | 101.2 | 101.5 | 101.5 | 101.7 | 100.0 | | | | | | | |
| 2 | 101.6 | 100.8 | 100.9 | 100.9 | 104.7 | 101.3 | 101.3 | 101.5 | 101.4 | 101.1 | 101.7 | 101.1 | 101.7 | 101.3 | 101.0 | | | | | | | |
| 3 | 100.8 | 100.8 | 100.7 | 100.3 | 101.4 | 103.6 | 101.2 | 101.1 | 100.0 | 100.5 | 101.4 | 101.2 | 100.6 | 100.7 | 101.2 | | | | | | | |
| 4 | 101.3 | 100.3 | 101.3 | 100.6 | 101.5 | 101.2 | 101.3 | 102.3 | 102.4 | 102.3 | 102.0 | 101.1 | 102.1 | 101.7 | 101.9 | | | | | | | |
| 5 | 100.2 | 101.2 | 100.9 | 100.8 | 100.5 | 102.9 | 100.8 | 101.5 | 102.5 | 102.4 | 102.2 | 102.1 | 101.2 | 102.2 | 101.0 | | | | | | | |
| 6 | 101.4 | 100.9 | 101.0 | 101.0 | 104.7 | 101.4 | 101.1 | 101.2 | 100.7 | 101.5 | 102.0 | 101.7 | 102.3 | 101.9 | 101.3 | | | | | | | |
| 7 | 100.6 | 101.2 | 100.7 | 100.4 | 101.7 | 102.3 | 101.6 | 102.4 | 101.4 | 101.4 | 102.4 | 100.9 | 101.9 | 102.1 | 100.9 | | | | | | | |
| 8 | 100.9 | 100.3 | 100.7 | 100.8 | 103.4 | 100.6 | 100.2 | 100.3 | 100.4 | 100.0 | 101.2 | 101.5 | 100.8 | 101.7 | 102.0 | | | | | | | |
| 9 | 101.4 | 100.8 | 100.8 | 101.3 | 104.6 | 101.4 | 101.2 | 100.4 | 100.0 | 99.9 | 100.6 | 100.0 | 101.2 | 100.7 | 100.5 | | | | | | | |
| 10 | 101.2 | 100.6 | 101.3 | 101.1 | 104.4 | 101.5 | 101.8 | 100.7 | 101.2 | 101.5 | 101.7 | 101.8 | 101.2 | 101.7 | 100.3 | | | | | | | |
| 11 | 100.9 | 100.1 | 101.0 | 101.3 | 103.8 | 101.0 | 101.3 | 101.7 | 100.7 | 100.6 | 100.4 | 101.5 | 101.3 | 101.2 | 100.7 | | | | | | | |
| 12 | 100.9 | 100.4 | 101.0 | 100.0 | 101.9 | 101.8 | 100.6 | 101.2 | 101.3 | 101.4 | 101.7 | 101.8 | 101.8 | 101.7 | 101.4 | | | | | | | |
| 13 | 100.6 | 99.9 | 100.3 | 100.1 | 100.8 | 100.8 | 101.3 | 100.1 | 101.3 | 100.7 | 101.2 | 101.0 | 101.0 | 101.4 | 101.0 | | | | | | | |
| 14 | 100.0 | 100.5 | 100.4 | 100.2 | 101.3 | 102.2 | 101.8 | 100.9 | 100.7 | 100.8 | 102.2 | 100.9 | 101.8 | 101.5 | 101.7 | | | | | | | |
| 15 | 101.5 | 101.0 | 101.0 | 100.9 | 101.3 | 102.0 | 100.8 | 100.8 | 100.6 | 100.1 | 100.8 | 101.4 | 100.9 | 101.0 | 100.4 | | | | | | | |
| 16 | 101.2 | 101.1 | 101.5 | 101.1 | 101.8 | 102.8 | 101.2 | 101.7 | 101.7 | 101.3 | 101.5 | 102.3 | 101.7 | 101.1 | 101.1 | | | | | | | |
| 17 | 101.2 | 100.8 | 100.9 | 101.5 | 102.9 | 101.9 | 101.2 | 100.8 | 101.1 | 100.9 | 101.0 | 100.6 | 101.4 | 100.0 | 100.3 | | | | | | | |
| 18 | 100.8 | 100.5 | 101.1 | 101.3 | 102.1 | 100.4 | 101.1 | 101.2 | 101.3 | 101.3 | 101.5 | 101.1 | 101.4 | 100.1 | 100.8 | | | | | | | |
| 19 | 100.8 | 100.4 | 100.8 | 101.1 | 103.8 | 103.1 | 101.5 | 102.8 | 102.5 | 102.6 | 102.6 | 101.9 | 102.1 | 102.3 | 101.9 | | | | | | | |
| 20 | 101.2 | 101.1 | 101.0 | 101.5 | 101.8 | 102.1 | 101.7 | 102.4 | 102.5 | 102.4 | 103.1 | 102.4 | 102.2 | 101.3 | 101.3 | | | | | | | |
| 21 | 100.3 | 100.0 | 100.5 | 101.7 | 104.1 | 101.8 | 101.9 | 102.2 | 102.5 | 101.7 | 101.4 | 100.8 | 100.7 | 100.7 | 99.9 | | | | | | | |
| 22 | 100.6 | 101.2 | 101.1 | 100.7 | 103.3 | 101.2 | 101.0 | 101.9 | 101.2 | 101.2 | 101.1 | 100.5 | 101.3 | 101.4 | 100.2 | | | | | | | |

DPC – Days post-challenge

FVR Post challenge Daily Body Temperature (°F)

| Vaccinates - Group 2 | | | | | | | | | | | | | | | |
|----------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | 100.0 | 101.1 | 100.4 | 100.7 | 101.7 | 101.3 | 100.2 | 100.7 | 101.5 | 101.6 | 101.3 | 101.2 | 101.4 | 101.5 | 100.0 |
| 2 | 100.8 | 101.0 | 100.6 | 100.7 | 101.7 | 101.2 | 101.6 | 101.2 | 101.1 | 101.1 | 101.3 | 101.5 | 101.8 | 100.7 | 101.0 |
| 3 | 100.6 | 101.4 | 100.8 | 101.9 | 101.6 | 101.8 | 100.9 | 102.0 | 102.4 | 102.2 | 102.7 | 102.5 | 102.0 | 102.5 | 101.1 |
| 4 | 100.9 | 100.2 | 100.7 | 100.4 | 102.7 | 101.5 | 100.2 | 101.9 | 101.7 | 101.9 | 102.1 | 101.9 | 100.0 | 102.7 | 101.6 |
| 5 | 100.4 | 100.1 | 101.0 | 100.3 | 102.0 | 101.4 | 101.2 | 101.7 | 101.7 | 101.6 | 101.5 | 101.6 | 101.9 | 100.8 | 100.6 |
| 6 | 101.7 | 100.9 | 101.5 | 100.7 | 104.6 | 102.7 | 101.9 | 102.2 | 100.6 | 101.3 | 102.3 | 101.1 | 101.3 | 100.6 | 101.5 |
| 7 | 100.7 | 100.1 | 101.3 | 100.7 | 101.4 | 102.2 | 101.0 | 101.2 | 100.4 | 101.0 | 101.2 | 100.6 | 100.6 | 100.4 | 100.2 |
| 8 | 100.7 | 100.6 | 101.1 | 101.1 | 103.1 | 101.7 | 102.2 | 102.5 | 102.3 | 101.4 | 102.3 | 102.6 | 101.6 | 101.8 | 101.7 |
| 9 | 101.8 | 101.3 | 101.6 | 100.5 | 102.8 | 103.2 | 102.7 | 102.1 | 102.5 | 102.6 | 102.2 | 102.6 | 102.8 | 101.6 | 101.8 |
| 10 | 100.6 | 100.6 | 100.7 | 102.5 | 102.9 | 101.9 | 102.0 | 102.6 | 102.4 | 101.3 | 101.5 | 101.5 | 101.9 | 100.8 | 100.4 |

Non-Vaccinated Controls

| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 1 | 100.7 | 101.1 | 101.2 | 100.4 | 102.0 | 105.0 | 102.0 | 105.0 | 101.4 | 102.2 | 101.3 | 101.7 | 101.8 | 100.0 | 100.8 |
| 2 | 101.0 | 100.3 | 101.1 | 100.6 | 101.4 | 103.3 | 101.2 | 102.3 | 103.2 | 101.8 | 102.5 | 102.5 | 101.2 | 102.2 | 100.0 |
| 3 | 101.3 | 101.5 | 102.0 | 101.2 | 101.6 | 105.3 | 101.2 | 101.8 | 103.5 | 103.5 | 101.6 | 100.5 | 101.3 | 101.9 | 101.7 |
| 4 | 101.5 | 100.7 | 101.3 | 101.2 | 103.6 | 101.7 | 104.0 | 102.0 | 102.7 | 101.1 | 101.1 | 101.6 | 101.4 | 101.2 | 101.1 |
| 5 | 102.1 | 101.4 | 101.7 | 101.4 | 102.1 | 103.5 | 101.0 | 104.7 | 101.5 | 102.6 | 101.4 | 101.4 | 102.4 | 100.8 | 100.6 |
| 6 | 101.6 | 101.3 | 101.3 | 100.5 | 103.0 | 101.8 | 102.6 | 103.6 | 103.4 | 100.7 | 101.7 | 101.0 | 102.2 | 100.5 | 101.0 |
| 7 | 101.3 | 100.4 | 101.2 | 100.9 | 104.6 | 101.3 | 102.8 | 102.0 | 103.0 | 100.5 | 101.3 | 101.8 | 101.7 | 100.0 | 100.5 |
| 8 | 101.1 | 100.3 | 101.4 | 100.7 | 103.7 | 102.5 | 103.9 | 102.4 | 102.4 | 101.2 | 101.4 | 101.9 | 101.8 | 100.6 | 101.7 |
| 9 | 100.5 | 100.0 | 100.9 | 100.0 | 102.0 | 100.9 | 101.2 | 105.5 | 101.8 | 102.3 | 102.4 | 101.5 | 101.4 | 101.1 | 100.0 |
| 10 | 101.5 | 101.4 | 101.6 | 101.1 | 103.8 | 102.2 | 104.3 | 102.2 | 102.0 | 100.6 | 101.4 | 100.8 | 100.7 | 100.9 | 100.0 |

DPC – Days post-challenge

| | |
|--|--|
| Study Type | Efficacy |
| Pertaining to | Feline Panleukopenia Virus (FPV) |
| Study Purpose | To demonstrate effectiveness against FPV |
| Product Administration | Two doses administered 21 days apart subcutaneously (SC) |
| Study Animals | Thirty-three (33) cats 8 weeks of age. Cats were randomized into one vaccinated group of 23 cats and one group of 10 non-vaccinated controls. |
| Challenge Description | 85 days post second vaccination all cats were challenged with virulent FPV. |
| Interval observed after challenge | Rectal temperatures and clinical signs were observed daily for 14 days post challenge. |
| Results | <p>Vaccinates and controls were evaluated for leukopenia (defined as $\geq 50\%$ decrease in white blood cells from pre-challenge levels).</p> <p>Positive for Leukopenia: Vaccinates: 0/0 (0%) positive Controls: 9/10 (90%) positive</p> <p>See the next page for data.</p> |
| USDA Approval Date | June 30, 1999 |

White Blood Cell Counts (counts/uL blood) Following FPV Challenge

Non-Vaccinated Controls

| Cat ID | Baseline Avg. | 2DPC | 4DPC | 6DPC | 8DPC | 10DPC |
|--------|---------------|-------|------|------|-------|-------|
| 1 | 18938 | 10890 | 8800 | 8360 | 7425 | 7810 |
| 2 | 11713 | 9405 | 6930 | 4125 | 5280 | 7865 |
| 3 | 12962 | 9735 | 4656 | 5610 | 3685 | 6325 |
| 4 | 11110 | 11000 | 4290 | 3630 | 4840 | 4510 |
| 5 | 12907 | 6105 | 4730 | 5555 | 6490 | 5005 |
| 6 | 15345 | 11440 | 3905 | 5280 | 9625 | 7425 |
| 7 | 14630 | 11550 | 5170 | 7095 | 7535 | 7920 |
| 8 | 13182 | 10945 | 5253 | 4565 | 8855 | 10340 |
| 9 | 12173 | 9240 | 7480 | 7810 | 8580 | 10120 |
| 10 | 12760 | 9405 | 8250 | 6050 | 15510 | 12045 |

Vaccinates

| Cat ID | Baseline Avg. | 2DPC | 4DPC | 6DPC | 8DPC | 10DPC |
|--------|---------------|-------|-------|-------|-------|-------|
| 11 | 14777 | 12155 | 21725 | 19305 | 20845 | 18040 |
| 12 | 12888 | 12650 | 9295 | 13090 | 13970 | 13475 |
| 13 | 11293 | 9955 | 11825 | 14410 | 12375 | 10505 |
| 14 | 10102 | 9955 | 10945 | 11275 | 12980 | 10725 |
| 15 | 8855 | 7590 | 8250 | 11550 | 11165 | 9295 |
| 16 | 13475 | 11165 | 11495 | 10120 | 10890 | 13365 |
| 17 | 10560 | 7755 | 15180 | 10450 | 13090 | 10505 |
| 18 | 17600 | 16354 | 18755 | 23650 | 18810 | 13255 |
| 19 | 16262 | 13145 | 14190 | 15785 | 16500 | 15950 |
| 20 | 12797 | 9625 | 12375 | 16280 | 15345 | 11825 |
| 21 | 14758 | 11660 | 12430 | 11770 | 11660 | 12430 |
| 22 | 14080 | 10560 | 10285 | 13145 | 17765 | 20570 |
| 23 | 10908 | 8690 | 7370 | 9900 | 11935 | 7810 |
| 24 | 13548 | 10010 | 11770 | 15685 | 12870 | 12760 |
| 25 | 13237 | 10395 | 11495 | 13585 | 18700 | 10505 |
| 26 | 13640 | 12320 | 14080 | 16225 | 15840 | 13860 |
| 27 | 13182 | 10615 | 12925 | 12650 | 16885 | 11303 |
| 28 | 10102 | 8140 | 8525 | 9405 | 12595 | 11880 |
| 29 | 11807 | 9570 | 17160 | 14350 | 11770 | 14465 |
| 30 | 13787 | 9625 | 17050 | 13255 | 14740 | 11743 |
| 31 | 13732 | 12870 | 17160 | 15180 | 15620 | 10780 |
| 32 | 10835 | 9515 | 15840 | 8305 | 11220 | 9900 |
| 33 | 12357 | 8414 | 17380 | 10065 | 11055 | 10450 |

DPC = Days Post Challenge

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | All fractions |
| Study Purpose | Demonstrate safety of product under typical use conditions |
| Product Administration | Either one or two doses of vaccine was administered 3 - 4 weeks apart by the subcutaneous route. A total of 1386 doses were administered. |
| Study Animals | A total of 716 cats, 282 eight weeks of age or younger and 434 greater than 8 weeks, received vaccine. Cats were privately owned and from commercial catteries. |
| Challenge Description | Not applicable |
| Interval observed after challenge | No challenge. Cats were observed for 30 minutes after vaccination and then daily for 2 weeks after each vaccination. |
| Results | Frequency of adverse events is summarized on the next page. |
| USDA Approval Date | October 29, 1998 |

Summary of Reactions:

| Reaction Type | up to 8 weeks of age | | | | > 8 Weeks of Age | | | | Sum of Doses | Percent |
|-------------------------|----------------------|------|---------------|-------|------------------|------|---------------|-------|--------------|---------|
| | <24h | >24h | Total by dose | % | <24h | >24h | Total by dose | % | | |
| None | NA | NA | 543 | 98.7% | NA | NA | 785 | 93.4% | 1328 | 95.82% |
| Fever | 0 | 0 | 0 | 0.00% | 2 | 0 | 2 | 0.24% | 2 | 0.14% |
| Lethargy | 3 | 0 | 3 | 0.55% | 14 | 0 | 14 | 1.67% | 17 | 1.23% |
| Vomiting | 1 | 0 | 1 | 0.18% | 2 | 0 | 2 | 0.24% | 3 | 0.22% |
| Diarrhea | 0 | 0 | 0 | 0.00% | 2 | 0 | 2 | 0.24% | 2 | 0.14% |
| Injection Site Soreness | 4 | 0 | 4 | 0.73% | 0 | 0 | 0 | 0.00% | 4 | 0.29% |
| Anorexia | | | | | | | | | 1 | 0.08% |
| Eye problem | | | | | | | | | 5 | 0.38% |
| Lost to follow-up | | | | | | | | | 10 | 0.72% |
| Unrelated Mortality* | | | | | | | | | 14 | 1.06% |
| Total Doses | | | 550 | | | | 836 | | 1386 | |

*Affirmed by licensee to have a non-vaccine cause.