



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	44B9.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live & Killed Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	CattleMaster 4+VL5 - No distributor specified
Date of Compilation Summary	February 21, 2023

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	Bovine Viral Diarrhea Virus, type 1 (BVDV 1)																																	
Study Purpose	Demonstrate efficacy against respiratory disease caused by BVDV 1																																	
Product Administration	Two doses administered intramuscularly 14 days apart																																	
Study Animals	Thirty-six (36) calves, at least 6 months of age; 24 vaccinates and 12 controls; seronegative for BVD																																	
Challenge Description	BVDV 1 virus (non-cytopathic type 1b strain New York-1)																																	
Interval observed after challenge	Clinical observations and rectal temperatures were collected for 3 days pre-challenge and 14 days post-challenge. Blood samples were collected 3 days prior day of challenge and for 14 days following challenge.																																	
Results	A scoring system for evaluation of responses of calves following challenge exposure was used:																																	
	<table><tr><th>Response to Challenge</th><th>Numerical Value (Point/day)</th></tr><tr><td>Temperature Elevation: Above 1.0°F</td><td>1</td></tr><tr><td>Above 2.0°F</td><td>2</td></tr><tr><td>Above 3.0°F</td><td>3</td></tr><tr><td>Leukopenia: 80-100 % of average leukocyte count</td><td>0</td></tr><tr><td>70-79.9 % of average leukocyte count</td><td>1</td></tr><tr><td>60-69.9 % of average leukocyte count</td><td>2</td></tr><tr><td>50-59.9 % of average leukocyte count</td><td>3</td></tr><tr><td>50% of average leukocyte count</td><td>4</td></tr><tr><td>Clinical Symptoms: Anorexia</td><td>3</td></tr><tr><td>Diarrhea</td><td>3</td></tr><tr><td>Death</td><td>20</td></tr></table>	Response to Challenge	Numerical Value (Point/day)	Temperature Elevation: Above 1.0°F	1	Above 2.0°F	2	Above 3.0°F	3	Leukopenia: 80-100 % of average leukocyte count	0	70-79.9 % of average leukocyte count	1	60-69.9 % of average leukocyte count	2	50-59.9 % of average leukocyte count	3	50% of average leukocyte count	4	Clinical Symptoms: Anorexia	3	Diarrhea	3	Death	20									
	Response to Challenge	Numerical Value (Point/day)																																
	Temperature Elevation: Above 1.0°F	1																																
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Clinical Symptoms: Anorexia	3																																	
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Death	20																																	
Total Scores based on points/day:																																		
<table><tr><th>Treatment Groups</th><th>Animal ID</th><th>Score</th></tr><tr><td rowspan="12">Controls</td><td>000</td><td>53</td></tr><tr><td>11-17</td><td>42</td></tr><tr><td>1-25</td><td>30</td></tr><tr><td>1-24</td><td>44</td></tr><tr><td>814</td><td>44</td></tr><tr><td>2-30</td><td>54</td></tr><tr><td>2-37</td><td>55</td></tr><tr><td>1-23</td><td>41</td></tr><tr><td>2-29</td><td>31</td></tr><tr><td>3-44</td><td>52</td></tr><tr><td>2-34</td><td>44</td></tr><tr><td>3-43</td><td>52</td></tr><tr><td rowspan="2">Vaccinates</td><td>818</td><td>13</td></tr><tr><td>805</td><td>11</td></tr></table>	Treatment Groups	Animal ID	Score	Controls	000	53	11-17	42	1-25	30	1-24	44	814	44	2-30	54	2-37	55	1-23	41	2-29	31	3-44	52	2-34	44	3-43	52	Vaccinates	818	13	805	11	
Treatment Groups	Animal ID	Score																																
Controls	000	53																																
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Vaccinates	818	13																																
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		008	25	
		407	7	
		108	21	
		722	16	
		727	6	
		802	8	
		314	19	
		22	0	
		71	19	
		706	0	
		750	11	
		289	6	
		66	3	
		72	7	
		701	13	
		283	3	
		137	9	
		826	0	
		717	20	
		11	19	
		93	10	
		353	22	
See next pages for individual data.				
USDA Approval Date	04/12/1984			

Rectal Temperatures in °F:

TG	ID	Days of Study (Challenge was on Day 0)														Total Score				
		-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10		11	12	13	14
Controls	000	101.4	101.1	100.9	101.6	101.5	101.6	101.6	102.8	101.9	101.9	101.8	105.5	101.7	101.5	101.6	101.5	101.4	101.5	4
	11-	100.9	100.8	101.2	100.6	101.2	101.2	101.1	101.8	101.8	101.4	103.7	103.3	101.9	101.9	101.5	102.0	101.5	101.7	5
	17																			
	1-25	101.5	101.4	101.6	101.7	101.5	101.5	102.6	102.3	101.6	101.7	104.2	101.8	102.7	101.8	101.8	101.9	101.1	102.3	3
	1-24	101.9	101.2	101.4	101.4	101.2	100.9	102.3	102.0	102.5	103.8	106.2	1-2.8	101.9	103.4	102.2	102.4	101.7	102.1	8
	814	101.4	101.5	101.4	101.3	101.7	101.5	103.2	101.8	102.3	101.7	104.4	102.3	101.9	102.4	102.4	102.2	102.0	101.3	6
	2-30	101.6	101.8	101.2	102.0	101.7	101.9	102.6	102.0	101.8	101.9	104.4	104.4	101.6	101.8	101.8	101.9	101.6	101.9	5
	2-37	101.5	101.2	101.5	101.4	101.4	102.4	102.2	103.3	103.4	102.8	105.9	103.5	102.9	102.7	102.2	102.2	101.1	102.7	13
	1-23	101.6	101.5	101.6	101.7	101.7	101.7	102.3	102.2	102.0	102.7	103.8	102.9	102.0	102.8	102.1	101.8	101.8	102.0	5
	2-29	101.3	101.6	101.8	101.2	101.4	101.6	102.7	101.8	101.8	102.5	103.7	104.9	102.0	101.6	101.8	101.9	101.6	101.9	5
	3-44	100.8	100.9	101.4	101.6	101.6	104.1	103.9	102.8	103.0	102.9	105.4	104.1	103.1	102.0	102.3	102.3	101.7	102.1	15
	2-34	101.8	101.7	101.2	101.0	101.2	101.5	102.6	102.6	101.8	102.3	105.0	103.9	102.9	102.1	102.0	101.5	101.8	102.9	8
	3-43	101.2	101.0	101.6	100.8	100.8	101.4	102.4	102.2	102.4	102.3	105.7	102.4	102.8	102.1	101.4	101.6	100.9	102.1	8
Vaccinates	818	102.3	101.7	101.7	101.9	101.7	101.9	101.9	103.1	102.4	101.9	102.3	105.3	102.7	101.7	101.7	101.8	101.3	101.3	3
	805	101.8	101.8	101.8	101.6	101.5	101.9	102.2	102.4	101.8	102.0	102.2	105.1	102.3	102.0	101.7	101.7	102.1	101.9	3
	008	101.9	101.8	101.4	101.9	101.7	102.3	102.7	102.0	102.2	102.5	102.2	105.2	102.0	102.0	102.0	101.9	101.9	101.7	4
	407	101.6	101.9	102.0	101.8	101.9	101.7	101.9	102.5	102.0	102.7	102.9	106.3	102.5	102.7	102.2	102.5	101.8	102.6	4
	108	101.6	101.7	101.4	102.1	102.5	102.7	102.3	102.2	101.8	102.3	102.1	103.4	102.8	102.3	102.5	102.6	102.9	103.5	6
	722	101.6	101.8	101.6	101.2	101.5	101.6	103.9	102.1	101.7	101.9	104.0	103.9	101.4	101.7	101.5	101.5	101.5	102.1	4
	727	101.3	101.5	101.4	100.7	101.0	101.0	101.2	101.7	101.3	102.0	102.5	104.6	101.6	101.5	101.3	101.1	101.2	101.5	3
	802	102.2	103.3	103.2	102.6	102.3	101.9	102.1	102.6	102.2	101.9	102.1	101.9	102.0	102.0	102.1	101.8	102.0	102.1	0
	314	101.7	102.0	101.7	101.5	101.5	101.9	102.8	102.3	101.9	102.3	103.6	104.9	101.6	102.0	102.0	102.1	101.5	101.6	8
	22	101.4	101.9	101.8	100.8	101.8	101.7	101.9	101.6	101.3	101.3	101.5	101.4	102.2	101.5	101.5	101.5	101.3	101.7	0
	71	101.3	101.6	101.5	100.6	101.6	101.3	101.4	101.1	100.7	101.2	103.9	105.1	100.7	100.9	101.0	101.1	101.2	101.7	5
	706	101.9	101.5	101.7	101.7	101.5	101.6	101.5	101.4	101.2	101.8	101.6	101.7	101.2	101.6	101.6	101.8	101.8	101.8	0
	750	101.9	101.7	102.2	101.8	101.7	101.6	101.6	102.4	102.1	102.0	102.9	106.6	101.7	101.5	101.3	101.2	101.4	102.4	5
289	101.4	102.1	102.0	101.7	101.9	101.9	102.6	100.5	101.2	101.6	101.6	101.7	101.5	101.5	101.7	101.7	102.1	102.3	1	
66	101.7	101.6	101.8	102.2	102.3	102.3	101.7	102.6	102.6	102.6	102.8	102.4	102.6	101.6	102.1	101.3	101.1	102.2	1	
72	101.5	101.6	101.6	101.0	101.5	101.8	102.2	100.9	101.5	102.6	101.6	106.6	101.9	102.4	102.0	101.6	101.2	102.2	4	
701	102.0	102.2	102.1	102.0	102.5	101.8	102.2	102.7	102.8	102.2	102.5	105.3	102.1	102.4	102.3	102.1	102.5	102.5	3	
283	101.4	101.5	101.2	101.2	101.4	101.2	103.0	101.4	100.9	101.6	101.3	101.4	101.6	101.3	101.5	100.9	101.0	101.9	1	
137	102.4	101.8	101.8	102.0	101.7	101.9	102.2	101.5	101.8	102.7	102.9	106.8	101.5	102.6	101.8	101.7	101.8	102.3	3	
826	102.1	102.1	102.7	102.5	102.0	102.5	102.0	102.1	102.1	102.4	101.4	101.9	102.2	102.4	102.3	102.0	102.6	102.7	0	
717	101.7	101.6	101.2	101.8	102.0	101.8	101.5	101.3	101.4	102.1	105.6	104.2	102.9	101.1	101.3	100.8	101.7	102.3	7	
11	102.2	102.3	102.1	102.0	101.9	102.1	102.7	103.0	102.0	102.3	103.8	105.0	102.4	102.5	101.5	102.3	101.4	101.7	3	
93	101.4	101.4	101.3	101.4	102.2	102.5	101.6	101.4	101.8	101.6	102.9	105.6	105.5	101.3	101.7	101.5	101.3	102.0	8	
353	101.8	101.9	102.0	101.5	102.1	101.1	103.3	103.8	101.8	103.6	102.4	104.3	102.3	103.7	101.9	102.1	102.9	101.9	7	

TG: Treatment group

White Blood Cell Count:

TG	ID	Days of Study (Challenge was on Day 0)														Total Score				
		-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10		11	12	13	14
Controls	000	12002	8034	7754	7920	8400	6516	4104	4549	5167	4858	5505	5428	7287	7269	7207	7671	7740	10106	28
	11-	8838	6477	7061	7024	6702	5072	2879	3859	5306	5413	5076	6204	6648	7258	6869	7322	7828	6622	13
	17																			
	1-25	10967	8370	8437	9169	8835	6188	4057	5787	6546	5410	5769	7799	6700	7943	7744	7807	10991	8662	15
	1-24	13093	10207	10401	11643	10534	8481	3931	7175	6447	5703	5792	8154	9924	10101	8733	9583	9264	10503	18
	814	10108	11588	10373	10319	9129	7184	3921	7376	7525	6121	5555	7065	6752	8360	6211	11737	13341	11836	23
	2-30	8928	9151	8136	6400	6844	5940	3489	4216	4548	3590	4621	5733	7630	7237	10041	6946	7942	7404	25
	2-37	7577	6937	6703	8732	7657	4099	4787	4601	4008	4291	8916	5547	4990	5080	5342	5622	5105	8376	21
	1-23	11045	8911	9128	9418	8804	6030	4424	4541	5776	6197	6116	7684	8948	8522	8188	10156	9713	9636	18
	2-29	11360	9442	7192	9812	9087	8094	4327	4868	6408	5424	6398	6169	6892	7866	6837	10937	7141	8849	20
	3-44	10671	10068	10140	9999	9358	6753	5436	7948	6603	6103	6478	9105	9434	7120	7408	10082	9201	9189	16
	2-34	10025	8550	7199	9053	7597	6871	4002	5591	5422	4628	5372	15617	5957	6345	6310	8501	9497	12473	18
	3-43	10714	9367	6812	7861	7210	4484	3982	4526	4446	2956	5536	8415	5367	5735	5102	6178	6322	8577	32
Vaccinates	818	9102	8300	7817	9705	9017	8499	8914	4926	6782	5610	5809	8118	13903	8069	8166	7112	7683	7623	7
	805	9437	9136	8082	8561	9093	8144	8154	5512	5506	5514	6660	6460	8598	7181	7939	7828	8391	8375	8
	008	10831	9151	9686	8914	6551	5988	7541	6470	5565	4837	5097	8159	9776	8975	7902	9765	8136	8569	18
	407	9789	7940	8169	7974	9128	8413	8949	5686	7270	6649	6955	7310	11362	8658	8593	8354	7277	7682	3
	108	7721	6963	7322	6424	6782	5764	7110	7469	4478	5390	7006	5155	7960	8293	10179	10369	8008	11273	5
	722	9360	9489	8951	12250	9868	8575	5525	5738	6660	5103	5654	9658	7247	8637	7488	7848	7776	8230	12
	727	9857	8528	8528	8054	9036	9316	7679	5989	8956	6082	6136	8045	9712	8069	8835	8345	7496	8847	3
	802	10742	9516	9724	8484	7989	7981	7506	8428	8464	7393	8332	7551	7343	7928	8564	9419	7244	8117	8
	314	11315	11871	12645	14417	12145	11813	7301	7103	8589	8199	7343	11835	11450	8916	13669	11776	10575	11405	11
	22	12960	12446	11311	11367	12603	11010	11369	10563	10412	10719	12259	14051	12513	11141	12102	10350	9923	10106	0
	71	8650	8197	7437	7889	8049	8966	7508	5522	5604	5116	5517	9407	11180	7182	7725	7009	6736	7769	8
	706	8504	8488	8272	10548	8688	10540	8800	8514	8777	7740	7784	8869	9225	8216	8598	8866	7191	8457	0
	750	9409	8073	5973	6995	7979	8681	7546	5103	5813	5988	5004	7383	11840	7922	8729	6119	6094	6363	6
	289	6245	6740	6532	6661	7498	4895	4954	4927	5344	6310	5192	5964	5135	6010	6199	6139	6044	6059	5
	66	8297	7876	6736	6325	5761	8465	10055	8821	6210	5669	6312	9291	10668	8908	8431	7081	7057	7968	2
	72	7316	7794	5892	7900	8227	7624	8181	6016	6634	4523	4962	6288	10917	7884	8883	7460	7199	6722	3
	701	8371	8610	8468	8015	8302	6760	6396	5237	7144	5475	5784	6622	10825	7844	7463	7175	6044	7675	10
	283	9410	9721	7688	8774	9953	8223	8510	7661	7891	7109	6076	7642	9311	9993	12522	11661	10711	10990	2
	137	10764	9534	8132	10768	10071	9124	8605	7509	5716	6642	11805	13752	9840	9259	7023	7700	7700	9006	6
	826	6786	6526	6957	7615	6928	6401	6421	6508	8248	6374	6245	6861	6777	2077	6884	7612	6108	7106	0
	717	10454	10440	9587	10495	8959	9594	6708	6173	7394	6524	5760	13417	11147	9638	8431	9051	10321	8686	10
	11	11067	9278	8896	7499	7599	8227	5385	5088	5411	5115	5371	8191	8362	7681	7245	8143	7806	7463	16
	93	10869	10007	8613	8974	9709	10072	9768	10636	10192	8189	6911	7423	10877	9286	10758	9684	8224	9049	2
	353	10854	10816	9548	9960	9642	10373	7877	8236	8391	5155	5340	7187	10712	8079	7447	7559	9343	7042	15

TG: Treatment group

Clinical Signs:

Treatment Groups	Animal ID	Days Post-Challenge														Total Score
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	000	N	N	N	A	D	D	AD	A	A	N	N	N	N	N	21
	11-17	N	N	N	A	D	AD	AD	A	D	N	N	N	N	N	24
	1-25	N	N	N	N	N	N	AD	D	D	N	N	N	N	N	12
	1-24	N	N	N	N	A	D	AD	AD	N	N	N	N	N	N	18
	814	N	N	N	N	A	N	AD	A	A	N	N	N	N	N	15
	2-30	N	N	N	A	A	D	AD	AD	D	N	N	N	N	N	24
	2-37	N	N	N	A	N	AD	AD	A	D	N	N	N	N	N	21
	1-23	N	N	N	N	N	D	AD	AD	D	N	N	N	N	N	18
	2-29	N	N	N	N	N	D	A	A	N	N	N	N	N	N	6
	3-44	N	N	N	N	D	N	AD	AD	AD	N	N	N	N	N	21
	2-34	N	N	N	N	N	N	AD	AD	AD	N	N	N	N	N	18
	3-43	N	N	N	N	N	N	A	A	AD	N	N	N	N	N	12
Vaccinates	818*															3
	805	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	008*															3
	407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	108	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	722	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	727	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	802	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	314	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	22	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	71*															6
	706	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	750	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	289	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	66	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	72	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	701	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	283	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	137	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	826	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	717*															3
	11	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	93	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	353	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0

N: Normal

D: Diarrhea

A: Anorexia

*: Missing data for individual days.

Study Type	Efficacy
Pertaining to	<i>Campylobacter fetus</i> (<i>C. fetus</i>)
Study Purpose	Demonstrate efficacy against campylobacteriosis caused by <i>C. fetus</i>
Product Administration	
Study Animals	
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	2/21/1980

Study Type	Efficacy																																																					
Pertaining to	Herpes virus, Bovine [Infectious bovine rhinotracheitis (IBR) virus]																																																					
Study Purpose	Demonstrate efficacy against respiratory disease caused by infectious bovine rhinotracheitis (IBR) virus																																																					
Product Administration	Two doses intramuscularly 21 days apart																																																					
Study Animals	Twenty-nine (29) calves: 24 vaccinates and 5 controls; seronegative for IBR																																																					
Challenge Description	Virulent IBR 14 days after second dose of vaccine																																																					
Interval observed after challenge	Temperatures and clinical observations were recorded 2 days before challenge and continuing until 14 days after challenge.																																																					
Results	A scoring system for evaluation of clinical responses as indices of severity of disease due to IBR virus infection was used: <table><tr><th>Response to Challenge</th><th>Numerical Value (Point/day)</th></tr><tr><td>Temperature Elevation: ≥ 1.0°F above average pre-challenge value ≥ 2.0°F above average pre-challenge value ≥ 3.0°F above average pre-challenge value</td><td>1 2 3</td></tr><tr><td>Clinical Symptoms: Nasal discharge Ocular discharge/Conjunctivitis Coughing/Audible rale/Heavy breathing</td><td>3 3 3</td></tr><tr><td>Death</td><td>20</td></tr></table> Total Scores based on points/day: <table><tr><th>Treatment Groups</th><th>Animal ID</th><th>Score</th></tr><tr><td rowspan="5">Controls</td><td>1419</td><td>30</td></tr><tr><td>1428</td><td>38</td></tr><tr><td>1455</td><td>67</td></tr><tr><td>1457</td><td>49</td></tr><tr><td>1474</td><td>56</td></tr><tr><td rowspan="15">Vaccinates</td><td>1324</td><td>1</td></tr><tr><td>1329</td><td>1</td></tr><tr><td>1332</td><td>1</td></tr><tr><td>1341</td><td>0</td></tr><tr><td>1345</td><td>0</td></tr><tr><td>1402</td><td>9</td></tr><tr><td>1405</td><td>1</td></tr><tr><td>1414</td><td>0</td></tr><tr><td>1415</td><td>0</td></tr><tr><td>1417</td><td>10</td></tr><tr><td>1421</td><td>0</td></tr><tr><td>1424</td><td>2</td></tr><tr><td>1426</td><td>1</td></tr><tr><td>1444</td><td>4</td></tr><tr><td>1446**</td><td>ND</td></tr></table>	Response to Challenge	Numerical Value (Point/day)	Temperature Elevation: ≥ 1.0°F above average pre-challenge value ≥ 2.0°F above average pre-challenge value ≥ 3.0°F above average pre-challenge value	1 2 3	Clinical Symptoms: Nasal discharge Ocular discharge/Conjunctivitis Coughing/Audible rale/Heavy breathing	3 3 3	Death	20	Treatment Groups	Animal ID	Score	Controls	1419	30	1428	38	1455	67	1457	49	1474	56	Vaccinates	1324	1	1329	1	1332	1	1341	0	1345	0	1402	9	1405	1	1414	0	1415	0	1417	10	1421	0	1424	2	1426	1	1444	4	1446**	ND
Response to Challenge	Numerical Value (Point/day)																																																					
Temperature Elevation: ≥ 1.0°F above average pre-challenge value ≥ 2.0°F above average pre-challenge value ≥ 3.0°F above average pre-challenge value	1 2 3																																																					
Clinical Symptoms: Nasal discharge Ocular discharge/Conjunctivitis Coughing/Audible rale/Heavy breathing	3 3 3																																																					
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	1474	56																																																				
Vaccinates	1324	1																																																				
	1329	1																																																				
	1332	1																																																				
	1341	0																																																				
	1345	0																																																				
	1402	9																																																				
	1405	1																																																				
	1414	0																																																				
	1415	0																																																				
	1417	10																																																				
	1421	0																																																				
	1424	2																																																				
	1426	1																																																				
	1444	4																																																				
	1446**	ND																																																				

		1447	5
		1448	0
		1458	0
		1464	1
		1468	0
		1473	0
		1476	0
		1479	0
		1480	3
		**: Animal died from strangulation ND: Not Determined	
See next pages for individual data.			
USDA Approval Date	06/24/1985		

Rectal Temperatures in °F:

Treatment Groups	Animal ID	Days of Study (Challenge was on Day 0)														Total Score			
		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11		12	13	14
Controls	1419	101.4	101.8	101.6	101.5	101.7	102.7	104.2	104.3	102.6	101.1	100.9	101.1	101.4	101.4	102.0	101.5	101.6	6
	1428	102.1	101.6	102.0	102.2	104.0	106.0	106.0	105.3	105.4	103.4	102.6	102.5	102.5	102.6	102.4	102.3	102.4	17
	1455	102.2	102.6	102.6	102.0	102.9	104.3	106.5	106.2	105.5	104.3	104.5	102.7	101.7	101.6	101.2	101.8	101.7	13
	1457	101.7	101.9	102.2	102.0	102.7	105.7	106.2	105.6	105.3	104.2	104.8	103.8	103.4	102.9	102.6	102.6	101.9	19
	1474	102.1	102.3	102.2	101.5	101.9	103.4	105.6	106.5	106.0	105.1	104.7	102.7	101.8	102.1	101.7	101.6	101.5	14
	1324	102.7	102.1	101.9	101.9	101.8	101.9	102.0	104.1	102.5	102.3	101.6	101.7	101.7	101.3	102.0	102.0	102.3	1
	1329	101.9	101.8	101.3	101.7	101.9	103.6	102.0	102.6	102.4	101.4	101.3	101.8	101.9	102.1	102.1	102.4	102.3	1
	1332	101.8	101.9	101.2	101.5	102.2	103.4	102.4	102.6	101.6	101.3	101.4	101.5	101.6	101.6	101.7	101.9	101.5	1
Vaccinates	1341	101.8	101.7	101.5	102.0	102.0	101.8	102.0	101.2	102.1	101.8	101.6	101.6	101.7	101.6	101.8	102.0	101.6	0
	1345	101.8	101.6	101.5	101.8	101.6	101.5	101.4	101.8	101.9	101.4	101.6	101.5	101.4	101.4	102.0	101.8	101.9	0
	1402	101.9	101.6	101.2	101.9	101.8	103.1	104.0	104.5	103.1	102.3	101.8	101.7	101.5	101.8	101.7	102.2	102.0	6
	1405	101.7	101.3	101.6	101.6	102.0	102.5	102.4	101.7	101.7	101.5	101.2	101.6	101.4	101.5	102.0	101.5	101.6	1
	1414	101.9	101.8	101.9	101.4	101.9	101.7	102.2	101.7	102.1	101.7	101.9	101.7	101.8	101.7	101.9	102.0	101.7	0
	1415	102.0	102.1	102.2	101.9	102.3	102.5	102.7	102.2	102.2	102.1	101.9	101.7	102.1	101.7	102.2	102.1	101.9	0
	1417	102.1	101.7	101.6	101.4	103.5	104.7	103.7	103.8	103.8	102.7	102.1	102.0	101.9	102.0	103.8	102.1	102.0	7
	1421	101.8	101.5	101.1	101.1	101.6	101.7	101.5	102.0	101.9	101.5	101.6	101.1	101.2	101.5	101.7	101.4	101.2	0
	1424	101.8	101.6	101.5	101.5	101.7	103.0	102.6	103.3	101.8	101.7	101.7	101.6	101.7	102.0	101.7	101.9	101.6	2
	1426	101.9	101.8	101.5	101.4	101.7	102.6	102.7	103.0	102.5	102.0	101.8	101.7	102.3	102.3	102.3	102.0	102.0	1
	1444	101.5	101.9	101.8	101.5	101.9	102.3	102.4	102.7	102.4	101.8	101.9	101.6	102.0	102.0	102.5	103.1	103.8	4
	1446*	101.6	101.5	101.6	101.8	101.7	102.2	102.0	102.0	-	-	-	-	-	-	-	-	-	-
	1447	101.6	101.5	101.5	101.5	102.6	103.6	103.2	103.2	101.6	101.7	101.6	101.5	101.7	101.5	101.5	101.7	101.7	5
	1448	101.7	101.7	101.6	101.5	101.4	101.2	102.3	102.2	102.0	101.4	101.3	101.3	101.6	101.6	102.2	101.9	101.9	0
	1458	101.5	101.8	101.7	101.5	101.9	101.9	102.4	102.3	101.9	101.5	101.6	101.6	101.7	101.9	101.9	101.9	101.9	0
	1464	102.5	101.9	101.8	101.9	101.9	102.9	102.3	102.6	102.5	102.0	101.9	101.8	101.8	101.9	101.9	101.9	103.0	1
1468	101.3	102.3	101.1	101.2	101.8	101.7	101.8	102.0	101.6	101.9	101.4	101.3	101.4	101.4	101.6	101.4	101.8	0	
1473	101.9	102.0	102.0	102.3	102.1	101.8	101.7	102.0	102.3	101.8	101.9	102.2	102.3	102.2	102.2	102.4	102.2	0	
1476	101.6	101.5	101.5	101.4	101.8	102.3	101.7	101.9	102.2	101.2	101.7	101.6	102.0	102.0	102.0	102.1	101.6	0	
1479	102.0	101.7	101.9	101.7	102.0	102.1	102.6	102.2	102.2	101.6	101.3	101.5	101.7	101.4	101.1	102.1	101.7	0	
1480	101.8	101.7	102.1	101.9	102.0	103.0	102.7	103.2	102.2	102.0	101.9	101.8	101.9	101.8	101.8	102.6	102.8	3	

*: Animal died from strangulation
 -: Not Determined

Clinical Signs of IBR Virus infection:

Treatment Groups	Animal ID	Days Post-Challenge														Total Score
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	1419	N	N	ND	OD ND	OD ND*	ND	ND	ND	N	N	N	N	N	N	24
	1428	N	ND	ND	ND	N	N	OD ND	OD	OD	N	N	N	N	N	21
	1455	N	ND	ND	OD ND HB	OD ND HB	ND HB	ND HB	ND HB	ND HB	ND	ND	N	N	N	54
	1457	N	N	OD	OD	OD ND	OD ND	OD ND	OD ND	N	N	N	N	N	N	30
	1474	N	ND	OD ND	ND	OD ND	ND	OD ND	OD	OD ND	OD	OD	N	N	N	42
Vaccinates	1324	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1329	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1332	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1341	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1345	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1402	N	N	N	ND	N	N	N	N	N	N	N	N	N	N	3
	1405	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1414	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1415	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1417	N	N	N	OD	N	N	N	N	N	N	N	N	N	N	3
	1421	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1424	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1426	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1444	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1446**	N	N	N	N	N	-	-	-	-	-	-	-	-	-	-
	1447	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1448	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1458	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1468	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1473	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1476	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1479	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0
	1480	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0

N: No visible signs of IBR virus infection

ND: Nasal Discharge

OD: Ocular discharge/lacrimation/conjunctivitis

HB: Heavy/labored breathing or audible rale

*: ND (blood)

**: Animal died from strangulation

-: Not Determined

Serum-neutralizing Antibodies against IBR Virus Following Vaccination and Challenge:

Treatment Groups	Animal ID	Serum-neutralizing Antibodies Titers ¹ Days Post-Vaccination			
		Day 0	Day 21	Day 35	Day 49
Controls	1419	<2	<2	<2	32
	1428	<2	<2	<2	90
	1455	<2	<2	<2	256
	1457	<2	<2	<2	90
	1474	<2	<2	<2	182
Vaccinates	1324	<2	<2	9	256
	1329	<2	<2	10	256
	1332	<2	<2	6	256
	1341	<2	3	12	362
	1345	<2	<2	12	512
	1402	<2	<2	<2	512
	1405	<2	<2	14	512
	1414	<2	<2	8	512
	1415	<2	<2	10	512
	1417	<2	<2	4	512
	1421	<2	3	17	256
	1424	<2	<2	8	256
	1426	<2	<2	7	256
	1444	<2	<2	11	256
	1446	<2	<2	14	ND ²
	1447	<2	<2	<2	128
	1448	<2	4	16	256
	1458	<2	<2	28	512
	1464	<2	<2	8	512
	1468	<2	<2	11	256
	1473	<2	<2	17	256
	1476	<2	<2	24	512
	1479	<2	<2	8	256
	1480	<2	<2	4	90

1: Serum-neutralizing antibody titers expressed as reciprocal of end-point dilution of serum

2: Not determined (ND) as the animal died from strangulation

Study Type	Efficacy
Pertaining to	<i>Leptospira interrogans</i> serovar <i>canicola</i> (<i>L. canicola</i>)
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>L. canicola</i>
Product Administration	One dose administered intramuscularly
Study Animals	15 Calves approximately 6 months of age; 10 vaccinates and 5 controls. All animals were seronegative for <i>Leptospira canicola</i> , <i>icterohaemorrhagiae</i> , <i>hardjo</i> , <i>grippotyphosa</i> , <i>pomona</i> .
Challenge Description	Animals were challenged 3 weeks following vaccination.
Interval observed after challenge	Animals were observed post challenge for 8 days. Body temperatures and blood samples were collected daily.
Results	<u>Leptospira Isolation Results in Blood:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive <u>Temperature Results:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive See the following tables for individual raw data
USDA Approval Date	09/13/1977

Blood culture for isolation of Leptospire:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)							
		1	2	3	4	5	6	7	8
CONTROLS	45	+	+	+	-	-	-	-	-
	68	+	+	-	-	-	-	-	-
	75	+	+	+	-	-	-	-	-
	86	+	+	-	-	-	-	-	-
	106	+	+	+	-	-	-	-	-
VACCINATES	39	-	-	-	-	-	-	-	-
	57	-	-	-	-	-	-	-	-
	63	-	-	-	-	-	-	-	-
	67	-	-	-	-	-	-	-	-
	82	-	-	-	-	-	-	-	-
	85	-	-	-	-	-	-	-	-
	92	-	-	-	-	-	-	-	-
	99	-	-	-	-	-	-	-	-
	103	-	-	-	-	-	-	-	-
	104	-	-	-	-	-	-	-	-

+: Leptospire detected; -: Leptospire not detected

Temperature in °F:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)								
		0	1	2	3	4	5	6	7	8
CONTROLS	45	102.4	101.0	104.4	107.2	106.2	103.6	103.8	101.6	100.8
	68	102.2	102.0	106.6	106.8	103.6	101.2	102.8	101.0	100.6
	75	102.0	102.0	102.0	106.6	106.4	101.4	101.6	101.6	101.8
	86	102.4	103.4	105.6	106.4	105.2	101.8	102.4	102.0	102.0
	106	102.0	102.0	104.0	104.8	104.4	102.8	101.6	101.4	101.0
VACCINATES	39	102.2	101.6	102.0	102.0	102.0	102.0	102.6	103.0	102.2
	57	101.2	102.0	101.4	101.0	101.0	100.2	100.8	100.8	100.2
	63	101.6	101.0	101.0	100.8	100.6	100.4	101.0	101.0	101.4
	67	102.0	102.0	101.6	101.0	101.4	101.8	101.8	101.6	102.0
	82	102.4	102.4	101.6	100.8	101.4	101.0	101.8	102.2	100.2
	85	100.8	102.8	101.4	100.4	100.6	100.2	100.6	101.0	100.8
	92	102.0	101.6	101.0	100.6	100.8	100.0	101.4	101.6	101.2
	99	102.0	102.0	101.4	101.8	102.0	101.4	101.6	101.6	100.6
	103	102.8	102.0	102.0	101.4	100.8	100.0	101.0	101.0	100.8
	104	101.8	101.6	102.0	101.2	101.2	101.2	101.4	101.4	100.6

Temperature >103 °F was considered as pyrexia

Study Type	Efficacy
Pertaining to	<i>Leptospira interrogans</i> serovar <i>grippotyphosa</i> (<i>L. Grippotyphosa</i>)
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>L. Grippotyphosa</i>
Product Administration	One dose
Study Animals	15 Calves; 10 vaccinates and 5 controls. All animals were seronegative for <i>Leptospira Grippotyphosa</i> , <i>hardjo</i> , <i>pomona</i> .
Challenge Description	Animals were challenged 8 weeks following vaccination.
Interval observed after challenge	Animals were observed for 8 days post challenge. Body temperatures and blood samples were collected daily.
Results	<u>Leptospira Isolation Results in Blood:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive <u>Temperature Results:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive See the following tables for individual raw data
USDA Approval Date	12/09/1975

Blood culture for isolation of Leptospire:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)							
		1	2	3	4	5	6	7	8
CONTROLS	161	+	+	+	+	+	-	-	-
	164	+	+	+	+	-	-	-	-
	165	+	+	+	+	-	-	-	-
	241	+	+	-	-	-	-	-	-
	248	+	+	+	-	-	-	-	-
VACCINATES	130	-	-	-	-	-	-	-	-
	137	-	-	-	-	-	-	-	-
	143	-	-	-	-	-	-	-	-
	145	-	-	-	-	-	-	-	-
	155	-	-	-	-	-	-	-	-
	247	-	-	-	-	-	-	-	-
	250	-	-	-	-	-	-	-	-
	255	-	-	-	-	-	-	-	-
	260	-	-	-	-	-	-	-	-
	261	-	-	-	-	-	-	-	-

+: Leptospire detected; -: Leptospire not detected

Temperature in °F:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)								
		0	1	2	3	4	5	6	7	8
CONTROLS	161	101.6	102.4	102.2	105.4	104.8	104.4	99.4	100.6	102.8
	164	101.4	101.8	105.8	104.6	106.4	103.6	101.4	101.4	101.4
	165	102.0	102.6	102.2	104.0	104.4	104.8	101.8	102.2	102.0
	241	102.2	101.8	101.2	105.4	103.8	104.2	100.4	101.0	101.2
	248	101.6	100.4	101.8	106.0	104.4	103.6	101.0	101.2	101.6
101.4VACCINATES	130	102.0	102.0	102.0	102.4	101.6	101.4	100.2	101.4	101.8
	137	101.6	101.8	101.8	102.0	101.8	101.4	100.6	100.8	101.0
	143	102.0	101.8	101.8	101.8	102.4	101.8	100.4	99.8	101.2
	145	102.0	101.4	101.4	101.8	102.4	101.6	99.6	101.2	101.4
	155	102.2	102.0	102.0	102.4	102.2	101.2	100.0	100.4	100.8
	247	101.4	100.8	101.6	101.6	101.6	101.8	100.0	100.6	100.8
	250	101.8	102.0	102.2	101.4	101.6	101.6	101.2	101.4	101.8
	255	102.4	101.8	101.8	102.6	102.2	102.4	101.8	102.0	101.4
	260	102.0	102.6	102.8	102.4	102.0	101.6	100.0	101.2	101.2
	261	102.2	100.6	101.2	101.4	101.4	101.0	100.2	100.4	100.6

Temperature >103.5 °F was considered as pyrexia

Study Type	Efficacy								
Pertaining to	<i>Leptospira hardjo</i> (<i>L. hardjo</i>)								
Study Purpose	Demonstrate efficacy against leptospirosis caused by <i>L. hardjo</i>								
Product Administration	One dose								
Study Animals	Sera (pre-vaccination and 3 weeks post-vaccination, 1:4 diluted and undiluted) from 20 vaccinated cattle were obtained and were administered intraperitoneally to hamsters. Four hamsters were used for each sera..								
Challenge Description	Hamsters were challenged with a virulent <i>L. hardjo</i> inoculate one day post administration of cattle sera.								
Interval observed after challenge	Hamsters were humanely euthanized 14 days post challenge and kidneys examined for <i>L. hardjo</i> culture.								
Results	<u><i>L. hardjo</i> Isolation in Hamster Kidneys Summary:</u> <table border="1"> <thead> <tr> <th>Cattle Sera</th><th>Hamsters Positive for <i>L. hardjo</i> / Tested (%)</th></tr> </thead> <tbody> <tr> <td>Pre vaccination</td><td>76/80 (95%)</td></tr> <tr> <td>1:4 dilution Post-vaccination</td><td>50/80 (62.5%)</td></tr> <tr> <td>Undiluted Post-vaccination</td><td>25/80 (31.25%)</td></tr> </tbody> </table> See table for individual data	Cattle Sera	Hamsters Positive for <i>L. hardjo</i> / Tested (%)	Pre vaccination	76/80 (95%)	1:4 dilution Post-vaccination	50/80 (62.5%)	Undiluted Post-vaccination	25/80 (31.25%)
Cattle Sera	Hamsters Positive for <i>L. hardjo</i> / Tested (%)								
Pre vaccination	76/80 (95%)								
1:4 dilution Post-vaccination	50/80 (62.5%)								
Undiluted Post-vaccination	25/80 (31.25%)								
USDA Approval Date	08/22/1978								

Bovine Serological Titers and Hamster Passive protection testing:

Cattle ID	Bovine Serological Titers		Hamster Kidney Isolations Positive / Total
354	Pre vaccination	-	4/4
	1:4 dilution		1/4
	Undiluted	64	0/4
355	Pre vaccination	-	4/4
	1:4 dilution		4/4
	Undiluted	4	1/4
358	Pre vaccination	-	3/4
	1:4 dilution		4/4
	Undiluted	16	2/4
359	Pre vaccination	-	4/4
	1:4 dilution		4/4
	Undiluted	32	0/4
390	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	8	3/4
361	Pre vaccination	-	4/4
	1:4 dilution		1/4
	Undiluted	64	1/4
375	Pre vaccination	-	3/4
	1:4 dilution		1/4
	Undiluted	128	1/4
376	Pre vaccination	-	4/4
	1:4 dilution		2/4
	Undiluted	128	0/4
381	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	16	3/4
382	Pre vaccination	-	4/4
	1:4 dilution		2/4
	Undiluted	32	0/4
357	Pre vaccination	4	4/4
	1:4 dilution		3/4
	Undiluted	32	3/4
386	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	32	2/4
389	Pre vaccination	-	4/4
	1:4 dilution		0/4
	Undiluted	32	0/4

394	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	16	1/4
No Ears	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	64	0/4
424	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	32	1/4
426	Pre vaccination	-	4/4
	1:4 dilution		3/4
	Undiluted	16	2/4
427	Pre vaccination	-	4/4
	1:4 dilution		4/4
	Undiluted	16	2/4
435	Pre vaccination	-	3/4
	1:4 dilution		0/4
	Undiluted	256	1/4
438	Pre vaccination	-	3/4
	1:4 dilution		3/4
	Undiluted	32	2/4

1:4 dilution Post-vaccination

Undiluted Post-vaccination

- is Negative

Study Type	Efficacy
Pertaining to	<i>Leptospira interrogans</i> serovar icterohaemorrhagiae (<i>L. icterohaemorrhagiae</i>)
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>L. icterohaemorrhagiae</i>
Product Administration	One dose administered intramuscularly
Study Animals	15 Calves approximately 6 months of age; 10 vaccinates and 5 controls. All animals were seronegative for <i>Leptospira canicola</i> , <i>icterohaemorrhagiae</i> , <i>hardjo</i> , <i>grippotyphosa</i> , <i>pomona</i> .
Challenge Description	Animals were challenged 7 weeks following vaccination.
Interval observed after challenge	Animals were observed for 8 days post challenge. Body temperatures and blood samples were collected daily.
Results	<u>Leptospira Isolation Results in Blood:</u> Controls: 4/5 (80 %) positive Vaccinates: 0/10 (0 %) positive <u>Temperature Results:</u> Controls: 5/5 (100 %) positive Vaccinates: 0/10 (0 %) positive See the following tables for individual raw data
USDA Approval Date	09/13/1977

Blood culture for isolation of Leptospire:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)							
		1	2	3	4	5	6	7	8
CONTROLS	66	+	+	-	-	-	-	-	-
	71	+	+	-	-	-	-	-	-
	79	+	+	+	-	-	-	-	-
	113	+	+	-	-	-	-	-	-
	120	-	-	-	-	-	-	-	-
VACCINATES	58	-	-	-	-	-	-	-	-
	69	-	-	-	-	-	-	-	-
	80	-	-	-	-	-	-	-	-
	102	-	-	-	-	-	-	-	-
	107	-	-	-	-	-	-	-	-
	114	-	-	-	-	-	-	-	-
	121	-	-	-	-	-	-	-	-
	122	-	-	-	-	-	-	-	-
	124	-	-	-	-	-	-	-	-
	128	-	-	-	-	-	-	-	-

+: Leptospire detected; -: Leptospire not detected

Temperature in °F:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)								
		0	1	2	3	4	5	6	7	8
CONTROLS	66	101.0	103.6	104.8	101.0	100.8	101.2	100.0	100.4	101.0
	71	101.0	104.0	102.0	102.2	101.8	101.4	100.4	102.0	101.4
	79	101.6	103.0	104.8	103.0	102.4	102.0	102.0	101.8	102.4
	113	101.4	104.4	104.2	102.8	100.8	100.2	101.0	101.2	101.4
	120	100.0	105.4	103.0	102.6	102.0	101.2	100.6	101.0	100.8
VACCINATES	58	99.8	101.6	101.4	101.4	101.8	101.6	101.0	101.2	102.4
	69	101.0	100.2	102.4	102.4	102.0	101.2	101.2	101.2	101.6
	80	101.4	101.8	101.4	101.0	102.0	101.6	100.6	101.0	101.6
	102	101.2	101.6	101.4	102.0	102.0	100.6	101.4	101.0	102.0
	107	101.2	102.0	101.8	99.8	101.8	101.0	100.8	101.6	101.4
	114	101.0	101.8	101.6	101.6	101.6	102.0	101.0	101.4	101.4
	121	101.4	101.8	102.0	101.8	101.8	101.4	102.0	101.2	102.2
	122	101.2	100.4	101.8	102.0	101.6	101.6	101.8	101.8	101.4
	124	101.4	101.4	101.4	101.0	101.6	100.8	101.0	101.2	101.8
	128	101.2	101.4	101.2	101.4	102.4	101.4	100.8	102.2	101.2

Temperature >103 °F was considered as pyrexia

Study Type	Efficacy
Pertaining to	<i>Leptospira interrogans</i> serovar <i>pomona</i> (<i>L. pomona</i>)
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>L. Pomona</i>
Product Administration	One dose
Study Animals	15 Calves; 10 vaccinates and 5 controls. All animals were seronegative for <i>Leptospira grippotyphosa</i> , <i>hardjo</i> , <i>pomona</i> .
Challenge Description	Animals were challenged 5 weeks following vaccination.
Interval observed after challenge	Animals were observed for 8 days post challenge. Body temperatures and blood samples were collected daily.
Results	<u>Leptospira Isolation Results in Blood:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive <u>Temperature Results:</u> Controls: 5/5 (100%) positive Vaccinates: 0/10 (0%) positive See the following tables for individual raw data
USDA Approval Date	12/09/1975

Blood culture for isolation of Leptospire:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)							
		1	2	3	4	5	6	7	8
CONTROLS	159	+	+	+	+	-	-	-	-
	163	+	+	+	-	-	-	-	-
	244	+	+	+	-	-	-	-	-
	252	+	+	+	-	-	-	-	-
	265	+	+	+	-	-	-	-	-
VACCINATES	134	-	-	-	-	-	-	-	-
	135	-	-	-	-	-	-	-	-
	142	-	-	-	-	-	-	-	-
	149	-	-	-	-	-	-	-	-
	151	-	-	-	-	-	-	-	-
	242	-	-	-	-	-	-	-	-
	245	-	-	-	-	-	-	-	-
	246	-	-	-	-	-	-	-	-
	257	-	-	-	-	-	-	-	-
	262	-	-	-	-	-	-	-	-

+: Leptospire detected; -: Leptospire not detected

Temperature in °F:

Treatment Group	Animal ID	Study Day (Challenge was on Day 0)								
		0	1	2	3	4	5	6	7	8
CONTROLS	159	102.6	102.2	104.6	105.8	106.2	103.4	100.8	102.0	102.8
	163	102.6	102.2	105.6	106.0	106.6	103.2	101.0	103.0	102.6
	244	101.6	102.2	103.2	104.6	103.8	102.4	101.8	101.8	102.4
	252	102.6	102.4	103.0	107.4	104.6	103.0	102.2	103.0	103.0
	265	101.8	102.8	103.6	106.4	105.6	103.0	102.0	103.8	102.0
101.4VACCINATES	134	102.2	101.4	101.6	101.6	102.0	102.2	101.4	102.0	103.0
	135	102.6	102.6	102.6	102.4	103.2	102.8	102.0	102.8	102.4
	142	102.6	102.6	101.6	102.0	102.0	102.8	99.8	102.2	102.6
	149	102.4	102.0	102.6	102.0	101.6	102.0	101.6	102.0	102.4
	151	101.6	101.4	102.0	101.4	101.4	101.6	101.4	102.2	101.8
	242	101.6	101.2	101.6	102.0	101.6	102.0	100.8	101.4	101.0
	245	102.8	102.6	102.4	102.0	101.8	102.6	101.0	102.6	102.8
	246	102.4	101.6	102.0	102.0	102.2	102.6	101.0	102.0	102.6
	257	102.2	101.6	101.0	101.6	102.0	101.6	101.2	101.6	101.0
	262	102.6	102.0	101.0	102.0	101.6	101.8	101.0	102.6	101.4

Temperature >103.5 °F was considered as pyrexia

Study Type	Efficacy																																																																	
Pertaining to	Bovine Parainfluenza type 3 Virus (PI ₃)																																																																	
Study Purpose	Demonstrate efficacy against respiratory disease caused by PI ₃																																																																	
Product Administration	Two doses intramuscularly with a 21-day interval between the injections.																																																																	
Study Animals	Thirty-three calves; 25 vaccinates and 8 controls. All controls were seronegative for PI ₃ , 3 vaccinates had low to medium level of neutralizing antibodies.																																																																	
Challenge Description	PI ₃ challenge 14 days post second vaccination																																																																	
Interval observed after challenge	Serum samples were collected on day 0 (first vaccination), day 8, day 21 (date of second vaccination), day 35, day 43 (8 days after challenge) and day 49 (14 days after challenge inoculation). Clinical observations, temperatures, and nasal swabs were collected daily for 14 days after challenge.																																																																	
Results	<u>Summary of Number of post-challenge days with positive PI₃ virus isolation:</u> <table><tr><th>Treatment Groups</th><th>Animal ID</th><th>Days</th></tr><tr><td rowspan="8">Controls</td><td>Y96/8</td><td>8</td></tr><tr><td>Y427/9</td><td>9</td></tr><tr><td>Y98/10</td><td>6</td></tr><tr><td>Y17/14</td><td>8</td></tr><tr><td>Y20/16</td><td>11</td></tr><tr><td>51</td><td>7</td></tr><tr><td>57</td><td>6</td></tr><tr><td>58</td><td>11</td></tr><tr><td rowspan="22">Vaccinates</td><td>R82/1</td><td>4</td></tr><tr><td>Y22/3</td><td>5</td></tr><tr><td>183/4</td><td>5</td></tr><tr><td>Y19/5</td><td>5</td></tr><tr><td>Y94/6</td><td>3</td></tr><tr><td>Y426/15</td><td>5</td></tr><tr><td>R86/17</td><td>5</td></tr><tr><td>Y23/22</td><td>5</td></tr><tr><td>Y93/32</td><td>5</td></tr><tr><td>Y97/36</td><td>7</td></tr><tr><td>R77/18</td><td>5</td></tr><tr><td>R78/19</td><td>5</td></tr><tr><td>R90/20</td><td>3</td></tr><tr><td>R85/21</td><td>1</td></tr><tr><td>R91/38</td><td>0</td></tr><tr><td>Y425/12</td><td>5</td></tr><tr><td>Y424/23</td><td>5</td></tr><tr><td>Y15/25</td><td>5</td></tr><tr><td>182/26</td><td>0</td></tr><tr><td>184/27</td><td>4</td></tr><tr><td>Y428/28</td><td>5</td></tr><tr><td>Y95/33</td><td>4</td></tr></table>	Treatment Groups	Animal ID	Days	Controls	Y96/8	8	Y427/9	9	Y98/10	6	Y17/14	8	Y20/16	11	51	7	57	6	58	11	Vaccinates	R82/1	4	Y22/3	5	183/4	5	Y19/5	5	Y94/6	3	Y426/15	5	R86/17	5	Y23/22	5	Y93/32	5	Y97/36	7	R77/18	5	R78/19	5	R90/20	3	R85/21	1	R91/38	0	Y425/12	5	Y424/23	5	Y15/25	5	182/26	0	184/27	4	Y428/28	5	Y95/33	4
Treatment Groups	Animal ID	Days																																																																
Controls	Y96/8	8																																																																
	Y427/9	9																																																																
	Y98/10	6																																																																
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	57	6																																																																
	58	11																																																																
Vaccinates	R82/1	4																																																																
	Y22/3	5																																																																
	183/4	5																																																																
	Y19/5	5																																																																
	Y94/6	3																																																																
	Y426/15	5																																																																
	R86/17	5																																																																
	Y23/22	5																																																																
	Y93/32	5																																																																
	Y97/36	7																																																																
	R77/18	5																																																																
	R78/19	5																																																																
	R90/20	3																																																																
	R85/21	1																																																																
	R91/38	0																																																																
	Y425/12	5																																																																
	Y424/23	5																																																																
	Y15/25	5																																																																
	182/26	0																																																																
	184/27	4																																																																
	Y428/28	5																																																																
	Y95/33	4																																																																

		Y18/34	0
		R83/35	0
		Y16/37	4
	See Individual data in the next tables.		
USDA Approval Date	03/10/1986		

Serological Response of Calves:

Treatment Groups	Animal ID	Sero-neutralizing Titers* on Days of Study (Day 0 is Day of First Vaccination, Day 35 is Day of Challenge)				
		0	8	21	35	49
Controls	Y96/8	< 2	< 2	< 2	< 2	512
	Y427/9	< 2	< 2	< 2	< 2	128
	Y98/10	< 2	< 2	< 2	< 2	384
	Y17/14	< 2	< 2	< 2	< 2	96
	Y20/16	< 2	< 2	< 2	< 2	192
	51	< 2	< 2	< 2	< 2	24
	57	< 2	< 2	< 2	< 2	384
	58	< 2	< 2	< 2	< 2	256
Vaccinates	R82/1	< 2	< 2	6	48	3072
	Y22/3	< 2	< 2	12	48	3072
	183/4	< 2	< 2	4	24	1536
	Y19/5	< 2	< 2	12	16	2048
	Y94/6	< 2	< 2	< 2	16	768
	Y426/15	< 2	< 2	4	24	768
	R86/17	2	2	12	24	1536
	Y23/22	< 2	< 2	12	32	1536
	Y93/32	< 2	< 2	< 2	8	768
	Y97/36	< 2	< 2	< 2	12	768
	R77/18	< 2	< 2	12	48	1536
	R78/19	< 2	< 2	48	48	3072
	R90/20	< 2	< 2	4	32	3072
	R85/21	< 2	2	32	96	2048
	R91/38	24	192	192	192	768
	Y425/12	< 2	< 2	4	12	1024
	Y424/23	< 2	< 2	24	48	4096
	Y15/25	< 2	< 2	64	48	4096
	182/26	< 2	6	32	48	1536
	184/27	< 2	2	48	16	1024
	Y428/28	< 2	< 2	4	12	4096
	Y95/33	< 2	< 2	< 2	4	1024
	Y18/34	< 2	< 2	32	256	3072
	R83/35	3	256	192	192	256
	Y16/37	< 2	< 2	24	48	1024

*Titer < 2 is considered seronegative

Virus Isolation from Nasal Swabs Obtained Daily from the Day of Challenge to Day 14:

Treatment Groups	Animal ID	Study Days post-Challenge														
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controls	Y96/8	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-
	Y427/9	-	+	+	+	+	+	+	+	+	+	-	-	-	-	-
	Y98/10	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
	Y17/14	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-
	Y20/16	-	+	+	+	+	+	+	+	+	+	+	+	-	-	-
	51	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
	57	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
	58	-	+	+	+	+	+	+	+	+	+	+	+	-	-	-
Vaccinates	R82/1	-	-	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y22/3	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	183/4	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y19/5	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y94/6	-	-	-	+	+	+	-	-	-	-	-	-	-	-	-
	Y426/15	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	R86/17	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y23/22	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y93/32	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y97/36	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
	R77/18	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	R78/19	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	R90/20	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-
	R85/21	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
	R91/38	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Y425/12	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y424/23	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y15/25	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	182/26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	184/27	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-
	Y428/28	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
	Y95/33	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-
	Y18/34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	R83/35	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Y16/37	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-

+: Virus was isolated; -: Virus was not isolated

Rectal Temperatures in °F:

Treatment Groups	Animal ID	Days of Study (Challenge was on Day 0)																	
		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	Y96/8	101.5	101.8	101.4	102.0	102.0	102.3	102.4	102.9	102.6	101.9	105.6	103.2	104.3	102.7	103.3	102.1	102.8	
	Y427/9	101.9	101.7	101.9	102.0	102.5	102.5	102.1	102.6	102.7	102.8	102.5	102.6	105.5	102.2	101.9	102.4	102.5	
	Y98/10	101.8	101.6	101.1	101.5	102.5	102.3	102.9	102.8	102.7	103.0	103.5	105.5	102.3	102.6	102.2	102.3	102.6	
	Y17/14	102.0	101.5	101.3	101.1	101.2	101.8	102.3	101.5	101.8	101.8	101.4	102.2	105.1	101.2	102.5	101.6	102.1	
	Y20/16	101.8	102.5	102.0	101.8	102.4	102.4	102.0	102.5	103.1	101.8	102.5	103.9	102.8	102.0	101.7	102.4	102.1	
	51	101.7	101.4	101.3	101.5	101.8	101.7	101.5	101.4	101.1	101.5	102.0	101.5	101.8	102.6	101.3	101.7	101.5	
	57	102.5	102.8	102.1	102.0	102.7	102.1	102.8	102.6	102.3	102.6	102.2	102.3	102.1	103.3	102.5	102.4	102.6	
	58	101.9	101.8	101.0	101.2	101.6	101.9	102.0	102.2	101.5	101.9	102.3	105.0	103.9	102.2	102.0	101.7	101.5	
	Vaccinates	R82/1	101.8	101.4	101.1	101.1	101.9	101.5	102.5	103.7	102.2	101.9	101.6	101.7	109.4	102.2	102.7	102.1	103.0
		Y22/3	102.5	102.1	101.8	102.2	102.0	101.9	102.1	102.3	102.6	103.0	103.1	103.1	103.3	102.3	101.7	102.4	101.8
183/4		102.1	101.6	101.6	101.5	101.7	101.9	101.8	101.8	101.5	101.9	101.8	105.5	103.6	101.7	101.7	101.5	101.3	
Y19/5		101.8	101.8	101.6	101.9	101.9	102.2	101.5	101.2	101.8	102.3	103.2	102.2	102.3	101.6	102.1	102.0	101.4	
Y94/6		102.2	101.9	102.1	102.0	102.0	102.2	103.5	102.6	102.4	102.0	105.5	102.7	103.5	102.6	103.0	103.2	102.6	
Y426/15		102.5	102.0	101.8	101.7	101.9	102.1	101.8	102.2	102.3	102.6	102.1	105.6	101.5	101.9	102.3	102.1	101.8	
R86/17		101.6	101.4	101.3	101.3	102.0	101.6	101.5	102.0	101.3	102.1	102.1	105.6	102.2	102.5	101.9	101.2	101.3	
Y23/22		101.8	101.4	101.4	101.6	101.6	102.5	101.4	102.3	101.9	101.7	103.7	102.7	102.3	101.4	101.9	101.3	101.5	
Y93/32		101.2	100.7	101.1	101.2	102.6	101.7	101.1	102.0	102.1	101.8	102.0	104.3	102.5	101.7	101.7	101.4	102.1	
Y97/36		101.7	101.3	101.3	101.6	101.8	101.7	100.9	101.5	101.7	101.5	101.4	101.9	102.1	102.0	102.2	106.5	102.0	
R77/18		101.2	101.6	101.9	101.9	101.8	101.8	101.6	101.8	101.6	101.5	101.3	101.6	102.1	101.8	101.7	101.7	101.6	
R78/19		101.8	101.6	101.5	101.6	102.0	101.4	101.5	101.7	101.7	101.5	101.7	101.8	102.0	101.8	101.7	101.9	101.8	
R90/20		101.8	102.1	101.2	101.6	102.4	102.2	101.7	102.1	101.7	102.0	101.6	101.5	101.8	101.2	102.0	101.5	101.5	
R85/21		102.3	102.0	101.3	101.6	101.6	101.4	101.6	101.6	101.6	101.4	101.4	101.9	102.3	101.8	101.5	106.1	103.1	
R91/38		101.9	101.5	101.7	101.4	101.5	101.9	100.9	101.2	101.0	100.8	101.1	101.1	101.2	101.6	101.7	101.4	101.3	
Y425/12		102.2	101.8	101.6	101.4	102.1	101.9	101.5	101.8	101.5	101.5	101.1	101.5	101.4	101.3	101.2	100.9	101.5	
Y424/23		101.8	101.3	101.4	101.7	102.2	102.4	102.2	101.6	101.3	101.1	101.5	101.5	101.4	101.9	101.7	101.4	101.3	
Y15/25		101.6	101.3	101.1	101.6	101.6	101.7	101.4	101.7	101.5	101.8	101.5	101.5	101.4	101.7	101.5	102.0	101.6	
182/26	102.1	101.9	101.3	101.2	101.8	101.7	102.2	101.6	101.0	101.8	101.8	101.3	101.5	101.8	101.8	101.5	101.8		
184/27	101.7	101.4	102.4	101.5	101.8	101.8	101.5	101.5	101.2	101.7	101.2	101.4	102.1	102.3	102.2	102.8	102.2		
Y428/28	102.3	102.0	102.0	101.2	102.4	102.2	101.9	102.4	101.9	102.1	101.9	102.1	102.4	102.3	102.8	102.6	102.1		
Y95/33	101.9	101.4	100.9	101.6	102.3	102.1	101.5	101.3	101.3	101.9	101.3	101.3	101.5	101.9	101.3	101.5	101.3		
Y18/34	101.6	101.3	101.4	101.7	102.2	102.3	101.3	101.5	101.5	101.3	101.3	101.7	101.6	101.2	101.6	101.6	101.7		
R83/35	101.9	101.6	101.4	101.4	101.8	101.4	101.0	101.1	101.2	101.5	101.5	101.4	101.4	101.9	101.4	101.3	101.3		
Y16/37	101.5	101.2	101.1	101.2	102.6	101.6	101.4	101.6	101.4	101.8	101.8	101.5	101.5	101.4	101.6	101.7	101.5		

Clinical Signs of PI₃ viral infection:

Treatment Groups	Animal ID	Days Post-Challenge													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controls	Y96/8	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y427/9	N	N	N	N	N	N	N	N	ND	ND	N	N	N	N
	Y98/10	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y17/14	N	N	N	N	N	N	N	N*	ND*	ND*	N	N	N	N
	Y20/16	N	N	N	N	N	ND	ND	ND	ND	N	N	N	N	N
	51	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	57	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	58	N	N	N	N	N	N	N	N	ND	ND	N	N	N	N
Vaccinates	R82/1	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y22/3	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	183/4	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y19/5	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y94/6	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y426/15	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R86/17	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y23/22	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y93/32	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y97/36	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R77/18	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R78/19	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R90/20	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R85/21	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R91/38	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y425/12	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y424/23	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y15/25	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	182/26	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	184/27	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y428/28	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y95/33	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y18/34	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	R83/35	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Y16/37	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N: No visible signs of PI₃ virus infection

ND: Nasal Discharge

*: Blood

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BRSV
Product Administration	Two doses Intramuscularly with the second dose 3 weeks after the first dose
Study Animals	32 calves; 24 vaccinates and 8 controls; Seronegative (<1:2) for BRSV.
Challenge Description	BRSV challenge 21 days after second vaccination
Interval observed after challenge	Nasal swabs samples were taken for 14 days post challenge for isolation. Clinical evaluations (depression, anorexia, coughing, sneezing, rhinorrhea, lacrimation, and respiratory distress) and temperature collections were conducted daily for 14 days post challenge.
Results	See individual data on next tables.
USDA Approval Date	02/17/1983

Isolation of Virus from Nasal Swabs Samples:

Treatment Groups	Animal ID	Days Post-Challenge													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controls	166	-	+	+	+	+	+	+	+	-	-	-	-	-	-
	176	-	+	+	+	+	+	+	+	-	-	-	-	-	-
	180	-	+	+	+	+	+	+	-	-	-	-	-	-	-
	186	-	+	+	+	+	+	+	-	-	-	-	-	-	-
	192	-	+	+	+	+	+	+	-	-	-	-	-	-	-
	198	-	-	-	+	+	+	+	-	-	-	-	-	-	-
	206	-	-	+	+	+	+	+	+	-	-	-	-	-	-
	207	-	-	+	+	+	+	-	-	-	-	-	-	-	-
Vaccinates	165	-	-	-	-	+	-	-	-	-	-	-	-	-	-
	167	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	169	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	170	-	-	+	+	+	-	-	-	-	-	-	-	-	-
	171	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	172	-	-	+	+	+	-	-	-	-	-	-	-	-	-
	173	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	177	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	179	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	181	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	183	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	185	-	-	+	+	+	+	+	-	-	-	-	-	-	-
	187	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	188	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	191	-	+	+	+	+	+	-	-	-	-	-	-	-	-
	193	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	195	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	199	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	200	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	203	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	205	-	-	+	+	+	+	-	-	-	-	-	-	-	-
	210	-	-	-	+	+	-	-	-	-	-	-	-	-	-
	212	-	-	+	+	+	-	-	-	-	-	-	-	-	-
	217	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Temperatures:

Treatment Groups	Animal ID	Study Days (Day 0 is challenge day)																		
			-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Controls	166	AM	101.6	100.4	101.6	101.3	101.0	101.1	103.5	102.2	102.0	102.0	102.0	101.4	102.1	105.6	101.5	100.7	101.6	100.1
		PM			102.0	101.0	101.8	101.2	102.5	101.6	102.0	101.4	102.7	101.9	104.3	101.7	102.1	101.7	101.2	
	176	AM	101.3	101.1	101.2	101.7	100.9	103.5	102.2	101.5	101.8	102.0	103.6	101.5	100.3	101.9	102.4	101.7	101.0	
		PM			101.0	102.0	101.5	102.3	101.3	101.7	102.6	102.0	102.8	102.2	100.5	102.8	102.2	101.8	102.1	
	180	AM	101.6	100.8	101.8	101.3	100.6	100.5	102.8	102.3	102.7	103.5	104.0	101.4	102.5	100.8	100.7	100.1	100.6	
		PM			102.6	101.6	100.6	101.2	103.6	101.1	102.9	102.2	105.0	102.2	102.0	100.7	100.2	100.0	101.0	
	186	AM	101.2	100.5	101.9	102.0	101.9	101.7	102.6	102.4	101.7	103.8	101.3	101.1	101.8	101.0	100.7	101.3	101.2	
		PM			102.0	101.8	102.0	101.3	103.2	101.4	101.2	102.1	100.2	101.4	102.5	101.0	101.0	101.7	101.7	
	192	AM	101.9	101.3	101.7	102.1	101.8	103.0	101.7	101.7	103.2	105.5	104.5	104.1	106.0	101.3	101.7	101.5	101.6	
		PM			101.6	101.8	101.2	103.1	101.2	101.1	105.3	105.5	104.1	103.7	102.8	101.6	102.3	101.4	101.5	
198	AM	101.5	100.8	102.4	102.0	101.6	101.9	101.8	101.5	102.1	102.6	102.2	101.9	101.2	101.3	101.3	101.6	101.4		
	PM			102.2	102.4	101.9	101.4	101.4	101.4	101.1	101.3	101.3	102.0	101.5	100.4	100.9	101.9	100.8		
206	AM	102.5	101.9	102.5	103.1	102.1	102.1	103.2	102.3	102.8	103.3	106.3	101.0	101.3	102.2	101.6	102.3	101.8		
	PM			102.6	103.0	101.8	103.5	102.0	101.4	103.9	103.3	103.4	102.4	103.7	102.3	101.6	102.4	101.4		
207	AM	101.0	100.0	101.2	101.6	100.2	100.3	105.1	101.1	103.7	102.8	105.3	101.5	100.9	104.0	101.2	100.8	101.3		
	PM			101.0	102.2	101.0	102.0	101.9	100.2	101.3	104.8	105.3	103.4	103.5	103.2	101.0	101.1	100.9		
Vaccinates	165	AM	98.7	98.8	102.1	102.2	100.5	99.7	100.7	101.0	100.9	101.6	101.4	100.6	101.0	98.9	99.8	100.5	101.0	
		PM			102.2	101.9	100.4	100.8	100.1	99.8	101.1	100.9	100.9	101.0	100.7	99.4	100.0	101.0	101.2	
	167	AM	100.8	101.0	101.5	101.8	101.2	101.6	101.7	101.5	102.4	101.9	101.6	101.4	101.7	100.3	101.0	101.2	101.6	
		PM			101.7	102.0	102.2	100.9	101.7	102.0	102.3	101.9	101.0	101.4	101.8	100.7	101.0	99.6	101.1	
	169	AM	100.0	100.3	101.2	102.0	101.7	101.7	102.0	101.9	101.7	102.2	103.5	104.9	102.4	102.2	102.1	102.4	102.1	
		PM			101.4	101.8	101.0	101.6	101.8	101.9	102.3	102.1	104.8	104.8	101.8	102.2	102.3	102.2	101.6	
	170	AM	100.4	100.7	102.0	101.8	102.1	101.8	101.4	101.5	100.8	101.6	101.6	102.8	101.2	100.3	100.4	101.3	101.3	
		PM			102.6	101.7	101.9	101.2	101.5	101.3	100.6	101.5	100.8	102.6	100.6	100.0	100.4	100.4	100.1	
	171	AM	99.4	100.8	101.5	102.1	101.6	100.8	101.2	101.0	101.2	101.4	101.5	103.2	100.7	100.4	100.3	100.6	100.5	
		PM			101.0	101.6	101.2	101.6	101.2	101.4	100.9	101.8	102.8	103.8	101.8	100.1	100.1	102.2	101.6	
	172	AM	100.6	100.4	101.4	102.1	101.6	101.5	102.0	102.1	101.0	101.6	105.4	101.3	100.7	99.3	99.6	101.1	100.9	
		PM			101.7	101.8	102.0	101.7	101.9	101.8	101.3	100.9	104.1	102.0	101.6	100.1	99.6	100.6	101.2	
	173	AM	98.9	100.1	101.6	102.0	101.6	101.2	101.1	101.5	101.3	103.6	101.5	102.3	103.2	101.6	101.3	100.9	100.8	
		PM			101.2	101.8	100.9	101.5	100.1	101.1	101.4	103.3	100.6	103.0	102.9	102.8	101.1	101.4	101.5	
	177	AM	101.0	102.6	102.8	102.7	102.7	101.8	102.6	102.8	102.4	102.7	103.5	102.8	101.8	100.4	101.3	101.3	101.6	
		PM			102.6	102.7	102.4	102.0	101.9	101.7	101.6	102.2	104.3	102.6	102.5	100.5	101.5	101.8	102.1	
	179	AM	100.4	100.2	101.3	102.7	100.7	101.2	101.4	102.0	102.9	102.4	101.8	104.0	101.3	100.8	99.9	100.0	101.5	
		PM			101.0	102.6	102.5	101.8	101.4	101.6	102.0	101.7	101.9	103.6	103.2	100.1	100.3	101.1	100.8	
	181	AM	100.3	100.4	101.7	102.0	101.5	101.5	103.3	101.7	102.0	101.8	101.4	102.6	101.4	102.2	102.5	100.8	101.6	
		PM			102.4	102.0	101.2	101.5	102.8	102.0	102.3	100.8	101.8	103.0	102.4	103.4	101.9	100.4	101.3	
	183	AM	100.5	101.1	101.0	101.4	101.9	101.4	101.5	101.4	101.2	102.8	101.6	101.3	102.2	101.2	100.5	100.6	100.6	
		PM			102.0	101.6	102.1	101.7	101.2	101.5	101.2	102.9	101.1	101.6	101.9	100.8	101.1	100.6	100.8	
	185	AM	101.0	101.7	102.2	102.3	101.7	100.7	104.3	103.4	102.8	101.7	102.0	102.2	102.1	101.3	101.4	101.9	101.7	
		PM			102.2	102.0	101.0	101.6	103.5	102.8	101.7	101.2	102.0	102.2	102.0	100.4	101.4	101.8	101.3	
	187	AM	101.2	102.0	102.0	102.2	102.1	102.2	102.2	102.5	101.6	102.8	105.0	101.8	102.0	101.1	101.5	101.7	102.0	
		PM			102.2	102.3	101.8	101.9	102.4	101.8	101.6	102.0	104.6	102.0	101.8	101.5	101.0	100.9	101.0	
	188	AM	101.9	101.5	102.2	101.7	102.1	102.0	102.0	101.3	100.5	101.9	102.1	102.9	102.0	100.3	100.1	101.0	101.5	
		PM			102.4	102.2	101.6	102.2	101.8	101.1	101.1	101.5	101.6	101.7	101.8	100.5	100.6	99.8	101.9	
	191	AM	100.1	100.4	102.3	102.2	101.6	101.9	101.7	103.4	101.8	101.9	102.9	105.0	100.5	101.3	101.3	101.4	100.8	
		PM			102.2	101.8	101.3	102.0	101.4	103.4	101.4	101.4	102.2	104.4	103.2	99.8	100.9	100.8	100.6	
	193	AM	101.7	101.8	102.2	102.5	101.5	100.4	102.0	103.7	102.6	103.1	101.9	101.9	103.6	99.7	100.7	101.5	101.4	
		PM			101.8	102.4	101.9	101.5	102.2	103.1	103.1	103.1	101.7	102.4	102.3	100.8	101.8	100.0	102.0	
	195	AM	100.9	101.1	102.4	102.1	102.0	102.5	102.6	103.0	102.9	102.9	104.2	103.0	103.8	103.5	101.7	101.7	103.0	
		PM			102.6	102.7	101.3	101.2	102.4	103.0	102.2	102.4	104.7	102.9	103.2	104.4	104.6	103.1	102.1	
	199	AM	100.5	100.4	102.5	102.2	102.1	101.9	102.5	102.9	102.0	102.5	104.6	101.9	102.6	101.8	101.5	101.7	101.7	
		PM			102.0	102.4	100.8	102.0	101.9	102.2	102.8	102.0	105.5	101.6	103.4	101.5	101.4	101.0	101.0	
	200	AM	100.0	99.6	103.1	102.5	101.7	102.1	101.8	101.8	102.1	102.2	102.5	103.4	101.8	101.3	102.3	101.8	102.0	
		PM			102.4	102.6	102.4	102.0	102.2	101.6	102.2	102.2	102.1	103.4	101.6	104.3	102.0	101.5	101.4	
	203	AM	98.0	99.6	102.1	102.2	101.7	101.0	102.2	102.2	102.6	101.8	101.7	101.4	100.1	100.0	100.4	100.7	100.4	
		PM			101.8	102.3	102.1	101.8	101.7	102.0	101.0	101.1	102.8	102.4	103.2	99.2	100.0	101.2	101.8	
	205	AM	100.2	101.0	101.8	102.5	102.0	102.4	101.8	102.1	101.5	102.1	102.5	102.9	102.2	101.2	101.8	101.2	101.1	
		PM			102.0	101.9	101.1	101.8	101.6	101.8	101.1	101.2	102.0	102.4	102.2	101.6	101.1	101.6	101.6	
	210	AM	100.4	100.4	101.5	102.0	101.4	101.7	102.0	101.9	101.3	101.6	101.2	103.2	101.9	99.0	100.1	100.8	101.2	
		PM			101.6	101.8	101.7	101.6	101.8	101.5	101.8	101.4	101.3	101.9	102.6	100.6	100.3	101.2	102.1	
	212	AM	99.8	101.2	101.6	102.9	102.4	102.3	101.7	103.5	100.9	102.8	103.5	103.5	102.8	101.1	102.3	101.3	101.3	
PM				101.0	102.6	101.9	101.9	101.3	101.6	101.2	101.9	103.8	103.6	102.8	102.3	102.1	101.7	101.6		
217	AM	100.3	99.8	100.3	101.5	100.5	102.0	100.7	101.1	100.4	101.3	100.6	100.3	10						

Clinical Evaluations:

Treatment Groups	Animal ID	Study Days (Day 0 is challenge day)																
		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controls	166	N	N	N	N	N	N	N	N	R	R	R	N	N	R	N	N	N
	176	N	N	N	N	N	N	N	N	R	R	C	R	RC	C	RC	RC	RC
	180	N	N	N	N	N	N	N	N	N	C	C	N	N	N	N	R	N
	186	N	N	N	N	N	N	N	N	N	R	C	N	R	N	N	C	N
	192	N	N	N	N	N	N	N	N	R	C	RC	N	N	C	C	N	N
	198	N	N	N	N	N	N	N	N	R	R	R	R	N	N	R	N	N
	206	N	N	N	N	N	N	N	N	N	N	R	R	R	RC	R	RC	R
	207	N	N	N	N	N	N	N	N	R	C	C	R	C	C	RC	RC	C
Vaccinates	165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	C	N	N
	167	N	N	N	N	N	N	N	N	N	N	RC	N	N	N	N	N	N
	169	N	N	N	N	N	N	N	N	N	N	N	N	C	N	N	C	N
	170	N	N	N	N	N	N	N	N	N	N	R	N	R	N	N	N	N
	171	N	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N	N
	172	N	N	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N
	173	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	177	N	N	N	N	N	N	N	N	R	N	R	N	N	R	R	N	N
	179	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	181	N	N	N	N	N	N	N	N	R	R	N	N	N	N	N	N	N
	183	N	N	N	N	N	N	N	N	N	N	R	N	N	N	C	C	N
	185	N	N	N	N	N	N	N	N	R	R	R	N	N	N	N	N	N
	187	N	N	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N
	188	N	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N	N
	191	N	N	N	N	N	N	N	N	R	R	R	N	N	R	R	R	N
	193	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N	N	N
	195	N	N	N	N	N	N	N	N	R	R	R	N	R	N	N	N	N
	199	N	N	N	N	N	N	N	N	R	N	RC	N	N	N	C	N	N
	200	N	N	N	N	N	N	N	N	R	R	RC	N	C	C	C	C	N
	203	N	N	N	N	N	N	N	N	N	N	R	N	N	N	N	N	N
	205	N	N	N	N	N	N	N	N	R	N	R	N	N	N	C	N	N
	210	N	N	N	N	N	N	N	N	N	N	C	N	N	N	N	N	N
	212	N	N	N	N	N	N	N	N	N	N	N	N	N	R	N	N	N
	217	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Code for clinical observations:

N = Normal

R = Rhinorrhea

C =Coughing

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety under field conditions
Product Administration	Two doses intramuscularly with the second dose 2 to 4 weeks after the first dose
Study Animals	A total of 8,235 heads of cows, heifers, and calves in 54 groups were included in the study: 3,968 vaccinated and 4,267 controls
Challenge Description	N/A
Interval observed after vaccination	Animals were observed on days 1-3, 7-14 after the first dose, at the time of second dose and 1-14 post second dose. Pregnant cows were to be observed throughout the remainder of gestation.
Results	Transient swellings at the injection site following vaccination were reported in 3 of the 54 groups that received the vaccine. No other adverse events were reported.
USDA Approval Date	12/28/1988