Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	49K5.R7
True Name	Porcine Circovirus Vaccine, Type 1 -Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fostera Gold PCV MH - No distributor specified
Date of Compilation Summary	September 26, 2018

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	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Efficacy against Porcine Circovirus type 2b
Product Administration	Two doses administered intramuscularly 3 weeks apart.
Study Animals	PCV2 serologically negative, commercial pigs, 3 days of age at first administration; 24 vaccinates and 25 controls.
Challenge Description	Porcine Circovirus 2 (PCV2b), 3 weeks after second vaccination.
Interval observed after challenge	PCV2 viremia (virus in serum) and PCV2 shedding in feces were evaluated twice weekly post challenge for 3 weeks. Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion).
Results	

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	3/24 (13%)	19/25 (76%)
Fecal Shedding (PCV2 detection in feces)	0/24 (0%)	20/25 (80%)
Lymphoid Depletion (PCV2 lesions)	1/24 (4%)	8/25 (32%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	1/24 (4%)	11/25 (44%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Raw data to follow:

Results (continued)

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
13	+	+	-	-
16	+	+	+	-
2	+	+	-	-
29	-	-	-	-
30	-	-	-	-
31	+	+	-	-
33	-	+	-	-
34	+	+	+	+
35	+	+	+	+
38	+	+	+	+
4	+	+	-	-
48	+	-	-	-
5	+	+	-	+
52	+	+	+	-
6	-	-	-	-
60	-	+	+	+
62	+	+	+	-
68	+	+	+	+
69	+	+	+	-
70	+	-	-	-
76	+	+	-	-
78	+	+	+	+
8	-	+	-	-
83	+	+	+	+
88	+	+	-	-

Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
1	-	-	-	-
10	-	-	-	-
11	-	-	-	-
12	-	-	-	-
14	-	-	-	-
15	-	-	-	-
23	-	-	-	-
26	-	-	-	-
27	-	-	-	-
28	-	-	-	-
36	-	-	-	-
43	-	-	-	-
50	-	-	-	-
51	-	-	-	-
55	-	-	-	-
65	+	-	+	+
66	+	-	-	-
67	+	-	-	-
7	-	-	-	-
72	-	-	-	-
74	-	-	-	-
79	-	-	-	-
86	-	-	-	-
9	-	-	-	-

Viremia, observed over time:

Control	Day 42-46	Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
13	-	-	+	-	+	-
16	-	+	+	+	+	+
2	-	+	+	-	+	-
29	-	-	-	-	-	-
30	-	-	-	-	-	-
31	-	-	+	-	-	-
33	-	-	-	-	-	-
34	-	+	+	+	+	+
35	-	-	+	+	-	-
38	-	-	+	+	+	-
4	-	+	+	+	-	-
48	-	-	+	-	-	-
5	-	+	+	+	+	-
52	-	-	+	+	-	-
6	-	-	-	-	-	-
60	-	-	-	-	-	-
62	-	+	+	+	+	-
68	-	+	+	+	+	-
69	-	+	+	+	+	-
70	-	-	-	+	-	-
76	-	-	+	+	+	-
78	-	-	+	+	+	+
8	-	-	-	-	-	-
83	-	-	+	+	+	-
88	-	+	+	+	+	-

Vaccinate	Day 42-46	Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
1	-	-	-	-	-	-
10	-	-	-	-	-	-
11	-	-	-	-	-	-
12	-	-	-	-	-	-
14	-	-	-	-	-	-
15	-	-	-	-	-	-
23	-	-	-	-	-	-
26	-	-	-	-	-	-
27	-	-	-	-	-	-
28	-	-	-	-	-	-
36	-	-	-	-	-	-
43	-	-	-	-	-	-
50	-	-	-	-	-	-

51	-	-	-	-	-	-
55	-	-	-	-	-	-
65	-	-	-	+	+	-
66	-	-	+	-	+	-
67	-	+	-	+	-	-
7	-	-	-	-	-	-
72	-	-	-	-	-	-
74	-	-	-	-	-	-
79	-	-	-	-	-	-
86	-	-	-	-	-	-
9	-	-	-	-	-	-

Fecal shedding, observed over time:

Control	Day 42-46	Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
13	-	-	+	+	-	-
16	-	+	+	+	+	+
2	-	-	+	+	-	-
29	-	-	-	-	-	-
30	-	-	-	-	-	-
31	-	-	+	+	-	-
33	-	-	+	-	-	+
34	-	+	+	+	+	+
35	-	-	+	+	+	-
38	-	-	+	+	+	-
4	-	+	+	+	-	+
48	-	-	-	-	-	-
5	-	-	-	+	+	-
52	-	-	+	+	+	+
6	-	-	-	-	-	-
60	-	-	-	+	-	-
62	-	-	+	+	+	+
68	-	-	-	+	+	+
69	-	-	+	+	+	+
70	-	-	-	-	-	-
76	-	-	+	+	+	+
78	-	+	+	+	+	+
8	-	-	-	+	-	+
83	-	-	+	+	+	+
88	-	-	+	+	-	+
All vaccinates were negative at all sampling points						

USDA Approval Date	April 07, 2017

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Pivotal efficacy against Porcine Circovirus type 2b
Product Administration	One dose, administered intramuscularly
Study Animals	PCV2 serologically negative, commercial pigs, 21 days of age at administration; 26 vaccinates and 14 controls.
Challenge Description	Porcine Circovirus 2 (PCV2b), 3 weeks after vaccination
Interval observed after challenge	PCV2 viremia (virus in serum) and PCV2 fecal shedding were evaluated twice weekly post challenge for 3 weeks. Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion).

Results

Results:

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	3/26 (12%)	10/14 (71%)
Fecal Shedding (PCV2 detection in feces)	7/26 (27%)	12/14 (86%)
Lymphoid Depletion (PCV2 lesions)	6/26 (23%)	11/14 (79%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	8/26 (31%)	12/14 (86%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Results (Continued)

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
122	+	+	+	+
146	+	+	-	-
153	+	+	+	+
167	+	+	+	+
188	+	+	+	+
193	-	-	-	-
202	-	+	+	+
214	+	+	+	+
25	+	+	+	+
358	-	-	+	+
368	+	+	+	-
378	+	+	+	+
48	+	+	+	+
78	-	+	+	+

Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
121	-	-	-	-
123	-	-	-	-
142	-	-	-	+
147	-	-	+	-
152	-	-	-	-
155	-	+	-	-
156	-	-	-	-
158	-	-	-	-
166	-	-	+	+
170	+	+	+	+
183	-	+	-	-
187	+	+	+	+
192	-	-	-	-
201	-	-	-	-
205	-	-	-	-
21	-	+	-	-
213	+	-	-	-
357	-	-	+	+
369	-	-	-	-
372	-	+	-	-
377	-	-	-	-
41	-	-	+	-
46	-	+	+	-
77	-	-	+	+
84	-	-	-	-
89	-	-	-	-

Raw data, by study day, shown below.

USDA Approval Date 09/15/2017

Viremia, observed over time:

		Study Day					
	Animal	24	28	31	35	38	42
Control	25	-	+	+	+	+	+
Control	48	-	+	+	+	+	+
Control	78	-	-	-	-	-	-
Control	122	-	-	+	+	+	-
Control	146	-	-	+	+	+	-
Control	153	-	-	+	+	+	+
Control	167	-	-	+	+	+	+
Control	188	-	-	-	+	+	+
Control	193	-	-	-	-	-	-
Control	202	-	-	-	-	-	-
Control	214	-	-	+	+	+	+
Control	358	-	-	-	-	-	-
Control	368	-	-	+	-	-	-
Control	378	-	-	-	+	+	-
Vaccinate	21	-	-	-	-	-	-
Vaccinate	41	-	-	-	-	-	-
Vaccinate	46	-	-	-	-	-	-
Vaccinate	77	-	-	-	-	-	-
Vaccinate	84	-	-	-	-	-	-
Vaccinate	89	-	-	-	-	-	-
Vaccinate	121	-	-	-	-	-	-
Vaccinate	123	-	-	-	-	-	-
Vaccinate	142	-	-	-	-	-	-
Vaccinate	147	-	-	-	-	-	-
Vaccinate	152	-	-	-	-	-	-
Vaccinate	155	-	-	-	-	-	-
Vaccinate	156	-	-	-	-	-	-
Vaccinate	158	-	-	-	-	-	-
Vaccinate	166	-	-	-	-	-	-

		Study Day					
	Animal	24	28	31	35	38	42
Vaccinate	170	-	-	+	-	-	-
Vaccinate	183	-	-	-	-	-	-
Vaccinate	187	-	+	+	-	-	-
Vaccinate	192	-	-	-	-	-	-
Vaccinate	201	-	-	-	-	-	-
Vaccinate	205	-	-	-	-	-	-
Vaccinate	213	-	-	+	-	-	-
Vaccinate	357	-	-	-	-	-	-
Vaccinate	369	-	-	-	-	-	-
Vaccinate	372	-	-	-	-	-	-
Vaccinate	377	-	-	-	-	-	-

Fecal shedding, observed over time:

		Study Day					
	Animal	24	28	31	35	38	42
Control	25	-	+	+	+	+	+
Control	48	-	+	+	+	+	+
Control	78	-	-	+	+	+	+
Control	122	-	-	+	-	+	-
Control	146	-	-	-	-	+	+
Control	153	-	-	-	+	+	+
Control	167	-	-	+	+	+	+
Control	188	-	-	-	+	+	-
Control	193	-	-	-	-	-	-
Control	202	-	-	-	+	-	-
Control	214	-	-	+	+	+	+
Control	358	-	-	-	-	-	-
Control	368	-	-	+	+	-	-
Control	378	-	-	-	+	+	+

		Study Day					
	Animal	24	28	31	35	38	42
Vaccinate	21	-	-	-	-	+	-
Vaccinate	41	-	-	-	-	-	-
Vaccinate	46	+	-	-	-	-	-
Vaccinate	77	-	-	-	-	-	-
Vaccinate	84	-	-	-	-	-	-
Vaccinate	89	-	-	-	-	-	-
Vaccinate	121	-	-	-	-	-	-
Vaccinate	123	-	-	-	-	-	-
Vaccinate	142	-	-	-	-	-	-
Vaccinate	147	-	-	-	-	-	-
Vaccinate	152	-	-	-	-	-	-
Vaccinate	155	-	-	-	-	-	+
Vaccinate	156	-	-	-	-	-	-
Vaccinate	158	-	-	-	-	-	-
Vaccinate	166	-	-	-	-	-	-
Vaccinate	170	-	-	+	-	-	+
Vaccinate	183	-	-	-	-	-	+
Vaccinate	187	-	-	+	-	-	-
Vaccinate	192	-	-	-	-	-	-
Vaccinate	201	-	-	-	-	-	-
Vaccinate	205	-	-	-	-	-	-
Vaccinate	213	-	-	-	-	-	-
Vaccinate	357	-	-	-	-	-	-
Vaccinate	369	-	-	-	-	-	-
Vaccinate	372	-	-	-	+	-	-
Vaccinate	377	-	-	-	-	-	-

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Pivotal efficacy against Porcine Circovirus type 2a
Product Administration	Two doses, administered intramuscularly, 3 weeks apart
Study Animals	PCV2 serologically negative, commercial pigs, 3 days of age at first administration; 30 vaccinates and 29 controls.
Challenge Description	Porcine Circovirus 2 (PCV2a), 3 weeks after second vaccination
Interval observed after challenge	PCV2 viremia (virus in serum) and PCV2 shedding in feces were evaluated twice weekly post challenge for 3 weeks. Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion and histiocytic replacement).
Results	**Results:**

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	1/30 (3%)	24/29 (83%)
Fecal Shedding (PCV2 detection in feces)	5/30 (17%)	25/29 (86%)
Lymphoid Depletion (PCV2 lesions)	1/30 (3%)	12/29 (41%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	2/30 (7%)	14/29 (48%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Results (Continued)

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
2	+	+	+	+
21	+	+	+	+
23	+	+	+	+
26	+	+	-	-
27	+	+	-	+
28	+	+	+	+
3	+	+	+	+
31	+	+	-	-
32	-	-	-	-
35	+	+	+	+
36	+	+	-	+
39	+	-	-	-
4	+	+	+	+
45	+	+	-	-
5	+	+	-	-
52	-	-	-	-
53	-	-	-	-
57	+	+	+	-
58	+	+	+	+
59	+	+	+	-
60	+	+	+	-
63	+	+	+	-
66	+	+	-	-
68	-	+	-	-
69	+	+	-	-
71	+	+	+	+
73	+	+	-	-
80	-	+	-	-
9	+	+	+	+

Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
1	-	+	-	-
10	-	-	-	-
11	-	-	-	-
12	-	+	+	-
16	-	-	-	-
17	-	-	-	-
18	-	-	-	-
19	-	+	-	-
20	-	-	-	-
25	-	-	-	-
29	-	+	-	-
30	-	-	-	-
37	-	-	-	-
38	-	-	-	-
40	-	-	-	-
47	-	-	-	-
49	-	+	-	-
50	-	-	-	-
55	-	-	-	-
56	-	-	-	-
6	-	-	-	-
61	-	-	-	-
64	-	-	-	-
65	-	-	+	-
67	-	-	-	-
70	-	-	-	-
72	-	-	-	-
8	-	-	-	+
83	+	-	-	-
84	-	-	-	-

Raw Data, by sampling day, presented below

USDA Approval Date	August 25, 2017

Viremia, observed over time:

		Study Day						
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Control	2	-	-	+	+	+	+	+
Control	3	-	-	+	+	+	+	+
Control	4	-	-	+	+	+	+	+
Control	5	-	-	+	-	-	-	+
Control	9	-	-	+	+	+	+	+
Control	21	-	-	+	+	+	+	+
Control	23	-	-	-	+	+	-	-
Control	26	-	-	+	+	-	-	-
Control	27	-	+	+	+	-	-	-
Control	28	-	-	+	+	-	-	-
Control	31	-	-	+	+	-	-	-
Control	32	-	-	-	-	-	-	-
Control	35	-	-	+	+	-	-	-
Control	36	-	-	+	+	-	-	-
Control	39	-	-	-	+	-	-	-
Control	45	-	-	-	+	-	+	-
Control	52	-	-	-	-	-	-	-
Control	53	-	-	-	-	-	-	-
Control	57	-	-	+	+	+	+	+
Control	58	-	-	+	+	-	-	-
Control	59	-	-	+	+	+	+	+
Control	60	-	-	+	+	-	+	-
Control	63	-	-	+	+	+	-	+
Control	66	-	-	+	+	+	+	+
Control	68	-	-	-	-	-	-	-
Control	69	-	-	-	-	-	+	+
Control	71	-	-	+	+	+	+	+
Control	73	-	-	+	+	-	-	-
Control	80	-	-	-	-	-	-	-

		Study Day						
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Vaccinate	1	-	-	-	-	-	-	-
Vaccinate	6	-	-	-	-	-	-	-
Vaccinate	8	-	-	-	-	-	-	-
Vaccinate	10	-	-	-	-	-	-	-
Vaccinate	11	-	-	-	-	-	-	-
Vaccinate	12	-	-	-	-	-	-	-
Vaccinate	16	-	-	-	-	-	-	-
Vaccinate	17	-	-	-	-	-	-	-
Vaccinate	18	-	-	-	-	-	-	-
Vaccinate	19	-	-	-	-	-	-	-
Vaccinate	20	-	-	-	-	-	-	-
Vaccinate	25	-	-	-	-	-	-	-
Vaccinate	29	-	-	-	-	-	-	-
Vaccinate	30	-	-	-	-	-	-	-
Vaccinate	37	-	-	-	-	-	-	-
Vaccinate	38	-	-	-	-	-	-	-
Vaccinate	40	-	-	-	-	-	-	-
Vaccinate	47	-	-	-	-	-	-	-
Vaccinate	49	-	-	-	-	-	-	-
Vaccinate	50	-	-	-	-	-	-	-
Vaccinate	55	-	-	-	-	-	-	-
Vaccinate	56	-	-	-	-	-	-	-
Vaccinate	61	-	-	-	-	-	-	-
Vaccinate	64	-	-	-	-	-	-	-
Vaccinate	65	-	-	-	-	-	-	-
Vaccinate	67	-	-	-	-	-	-	-
Vaccinate	70	-	-	-	-	-	-	-
Vaccinate	72	-	-	-	-	-	-	-
Vaccinate	83	-	-	-	+	-	-	-
Vaccinate	84	-	-	-	-	-	-	-

Fecal Shedding, observed over time:

		Study Day						
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Control	2	-	-	+	+	+	+	+
Control	3	-	-	+	+	+	+	+
Control	4	-	-	+	+	+	+	+
Control	5	-	-	+	+	+	+	+
Control	9	-	-	+	+	+	+	+
Control	21	-	-	+	+	+	+	+
Control	23	-	-	+	+	+	+	-
Control	26	-	-	+	+	+	+	+
Control	27	-	+	+	+	+	-	+
Control	28	-	+	+	+	+	+	+
Control	31	-	-	+	+	+	-	+
Control	32	-	-	-	-	-	-	-
Control	35	-	-	+	+	+	-	-
Control	36	-	-	+	+	-	+	+
Control	39	-	-	-	-	-	-	-
Control	45	-	-	-	+	+	+	-
Control	52	-	-	-	-	-	-	-
Control	53	-	-	-	-	-	-	-
Control	57	-	-	+	+	+	+	+
Control	58	-	-	+	+	-	-	-
Control	59	-	-	+	+	+	+	+
Control	60	-	-	-	+	+	-	+
Control	63	-	-	+	+	+	+	+
Control	66	-	-	+	+	+	+	+
Control	68	-	-	-	-	+	+	+
Control	69	-	-	+	+	+	+	+
Control	71	-	-	+	+	+	+	+
Control	73	-	-	+	-	+	-	-
Control	80	-	+	+	-	+	-	-

		Study Day						
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Vaccinate	1	-	-	+	-	-	-	-
Vaccinate	6	-	-	-	-	-	-	-
Vaccinate	8	-	-	-	-	-	-	-
Vaccinate	10	-	-	-	-	-	-	-
Vaccinate	11	-	-	-	-	-	-	-
Vaccinate	12	-	-	-	-	+	-	-
Vaccinate	16	-	-	-	-	-	-	-
Vaccinate	17	-	-	-	-	-	-	-
Vaccinate	18	-	-	-	-	-	-	-
Vaccinate	19	-	-	+	-	-	-	-
Vaccinate	20	-	-	-	-	-	-	-
Vaccinate	25	-	-	-	-	-	-	-
Vaccinate	29	-	+	-	-	-	-	-
Vaccinate	30	-	-	-	-	-	-	-
Vaccinate	37	-	-	-	-	-	-	-
Vaccinate	38	-	-	-	-	-	-	-
Vaccinate	40	-	-	-	-	-	-	-
Vaccinate	47	-	-	-	-	-	-	-
Vaccinate	49	-	-	+	+	-	-	-
Vaccinate	50	-	-	-	-	-	-	-
Vaccinate	55	-	-	-	-	-	-	-
Vaccinate	56	-	-	-	-	-	-	-
Vaccinate	61	-	-	-	-	-	-	-
Vaccinate	64	-	-	-	-	-	-	-
Vaccinate	65	-	-	-	-	-	-	-
Vaccinate	67	-	-	-	-	-	-	-
Vaccinate	70	-	-	-	-	-	-	-
Vaccinate	72	-	-	-	-	-	-	-
Vaccinate	83	-	-	-	-	-	-	-
Vaccinate	84	-	-	-	-	-	-	-

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Efficacy against Porcine Circovirus type 2a.
Product Administration	One dose, administered intramuscularly.
Study Animals	PCV2 serologically negative, commercial pigs, 3 weeks of age at administration; 28 vaccinates and 29 controls.
Challenge Description	Porcine Circovirus 2 (PCV2a), 3 weeks after vaccination.
Interval observed after challenge	PCV2 viremia (virus in serum) and PCV2 fecal shedding were evaluated twice weekly post challenge for 3 weeks. Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion).
Results	

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	1/28 (4%)	22/29 (76%)
Fecal Shedding (PCV2 detection in feces)	7/28 (25%)	22/29 (76%)
Lymphoid Depletion (PCV2 lesions)	0/28 (0%)	9/29 (31%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	0/28 (0%)	13/29 (45%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Raw data to follow:

Results (continued)

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
2457	+	+	+	+
2464	+	+	+	-
4850	+	+	-	-
5638	-	-	-	-
5645	+	-	-	-
5647	+	+	-	-
5650	+	+	+	+
5652	+	+	+	+
5653	+	+	+	-
5658	+	+	-	-
5684	+	+	-	+
5700	+	+	+	-
5707	-	-	-	-
5710	+	+	+	+
5713	-	+	-	-
5716	+	+	-	-
5723	+	+	+	+
5726	-	-	-	-
5762	+	-	-	-
6503	-	-	-	-
6515	-	-	-	-
6526	-	+	-	-
6542	+	+	+	-
6552	+	+	-	-
6564	+	+	+	+
6565	+	+	+	+
6572	+	+	+	-
6589	+	+	-	-
6599	+	+	+	+

Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
2463	-	-	-	-
4851	-	+	-	-
4852	-	-	-	-
5644	-	-	-	-
5649	-	-	-	-
5654	-	-	-	-
5679	-	+	-	-
5686	-	-	-	-
5699	-	-	-	-
5705	-	-	-	-
5717	-	-	-	-
5719	-	+	-	-
5720	-	-	-	-
5725	-	+	-	-
5760	-	-	-	-
5761	-	-	-	-
5766	-	+	-	-
5767	-	-	-	-
6519	-	-	-	-
6524	-	-	-	-
6527	-	-	-	-
6534	-	+	-	-
6540	-	-	-	-
6545	+	-	-	-
6560	-	-	-	-
6568	-	-	-	-
6581	-	-	-	-
6582	-	+	-	-

USDA Approval Date September 26, 2016

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Pivotal efficacy against Porcine Circovirus type 2
Product Administration	Two doses, administered intramuscularly, 3 weeks apart.
Study Animals	PCV2 serologically negative, commercial pigs, 3 weeks of age at first administration; 29 vaccinates and 27 controls.
Challenge Description	Porcine Circovirus 2 (PCV2a), 3 weeks after second vaccination.
Interval observed after challenge	PCV2 viremia (virus in serum) and PCV2 fecal shedding were evaluated weekly post challenge for 3 weeks. Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion and histiocytic replacement).
Results	

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	0/29 (0%)	25/27 (93%)
Fecal Shedding (PCV2 detection in feces)	7/29 (24%)	25/27 (93%)
Lymphoid Depletion (PCV2 lesions)	0/29 (0%)	4/27 (15%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	0/29 (0%)	3/27 (11%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Raw data to follow:

Results

(continued)

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
1102	+	+	-	-
1103	+	+	-	-
1107	+	+	-	-
1108	+	+	-	-
1111	+	+	+	-
1114	+	+	-	-
1117	+	+	-	+
1121	+	+	-	-
1125	-	-	-	-
1126	+	+	-	+
1131	+	+	+	+
1135	+	+	-	-
1138	+	+	-	-
1145	+	+	+	+
1146	+	+	-	-
1150	+	+	-	-
1153	-	+	-	-
1154	+	+	-	-
1159	+	+	-	-
1169	+	+	-	-
1170	+	-	-	-
1176	+	+	-	-
1178	+	+	-	-
1181	+	+	-	-
1188	+	+	-	-
1195	+	+	-	-
1199	+	+	-	-

Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
1101	-	+	-	-
1104	-	+	-	-
1105	-	-	-	-
1106	-	-	-	-
1112	-	-	-	-
1115	-	-	-	-
1118	-	-	-	-
1123	-	+	-	-
1124	-	-	-	-
1127	-	+	-	-
1132	-	-	-	-
1133	-	+	-	-
1134	-	-	-	-
1143	-	-	-	-
1147	-	-	-	-
1148	-	-	-	-
1149	-	+	-	-
1151	-	-	-	-
1155	-	-	-	-
1156	-	-	-	-
1158	-	-	-	-
1167	-	-	-	-
1171	-	-	-	-
1172	-	+	-	-
1177	-	-	-	-
1180	-	-	-	-
1191	-	-	-	-
1194	-	-	-	-
1198	-	-	-	-

USDA Approval Date	September 13, 2013

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
Study Purpose	Duration of immunity against Porcine Circovirus 2.
Product Administration	One dose, administered intramuscularly.
Study Animals	PCV2 serologically negative, commercial pigs, 3 weeks of age at administration; 28 vaccinates and 26 controls.
Challenge Description	Porcine Circovirus 2 (PCV2b), 23 weeks after vaccination.
Interval observed after challenge	PCV2 viremia (virus in serum) was evaluated twice weekly, and fecal shedding was evaluated weekly, for 30 days after challenge. Lymphoid tissues were evaluated 30 days post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion and histiocytic replacement).
Results	

Variable	Vaccinates Ever Positive*	Controls Ever Positive*
Viremia (PCV2 detection in serum)	0/28 (0%)	15/26 (58%)
Fecal Shedding (PCV2 detection in feces)	5/28 (18%)	16/26 (62%)
Lymphoid Colonization (PCV2 in lymphoid tissues)	1/28 (4%)	9/26 (35%)

*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Raw data to follow:

Results (continued)	Control ID	viremia	fecal shedding	lymphoid colonization	Vaccinate ID	viremia	fecal shedding	lymphoid colonization
	502	+	+	+	501	-	-	-
	505	+	+	-	503	-	-	-
	506	-	-	-	504	-	-	-
	507	-	+	-	508	-	-	-
	509	+	+	+	510	-	-	-
	512	-	-	-	511	-	+	-
	513	-	-	-	514	-	-	-
	515	+	+	+	516	-	-	-
	517	-	-	-	518	-	-	-
	522	+	+	-	519	-	+	-
	524	+	+	+	521	-	-	-
	526	+	+	-	523	-	+	+
	527	-	-	-	525	-	-	-
	528	+	+	+	529	-	-	-
	531	-	+	-	530	-	-	-
	533	-	+	-	532	-	-	-
	538	+	-	-	536	-	-	-
	545	+	+	-	539	-	-	-
	546	-	-	-	540	-	-	-
	547	+	+	+	542	-	-	-
	548	+	-	+	543	-	+	-
	550	-	-	-	544	-	-	-
	552	+	+	-	549	-	+	-
	558	-	-	-	551	-	-	-
	559	+	+	+	553	-	-	-
	560	+	+	+	554	-	-	-
					555	-	-	-
					556	-	-	-
USDA Approval Date	June 6, 2014							

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Circovirus, porcine, type 2 (PCV2)</td></tr>
<tr><td>Study Purpose</td><td>Duration of Immunity against Porcine Circovirus Type 2b</td></tr>
<tr><td>Product Administration</td><td>One dose, administered intramuscularly.</td></tr>
<tr><td>Study Animals</td><td>PCV2 serologically negative, commercial pigs, 3 weeks of age at administration; 25 vaccinates and 25 controls.</td></tr>
<tr><td>Challenge Description</td><td>Porcine Circovirus Type 2b, 23 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>PCV2 viremia and PCV2 Fecal Shedding were evaluated twice weekly post challenge for 3 weeks.

Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 in lymphoid tissues and characteristic lesions attributable to PCV2 disease (lymphoid depletion and histiocytic replacement).</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Variable</th><th>Vaccinates Ever Positive*</th><th>Controls Ever Positive*</th></tr>
<tr><td>Viremia
(PCV2 detection in serum)</td><td>4/25 (16%)</td><td>13/25 (52%)</td></tr>
<tr><td>Fecal Shedding
(PCV2 detection in feces)</td><td>3/25 (12%)</td><td>20/25 (80%)</td></tr>
<tr><td>Lymphoid Depletion
(PCV2 lesions)</td><td>3/25 (12%)</td><td>11/25 (44%)</td></tr>
<tr><td>Lymphoid Colonization
(PCV2 in lymphoid tissues)</td><td>0/25 (0%)</td><td>6/25 (24%)</td></tr>
</table>
*A pig was considered positive for PCV2 detection in serum or feces if it had a positive result at any sampling point.

Raw data to follow:</td></tr>
<tr><td>USDA Approval Date</td><td>04/12/17</td></tr>
</table>

Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion	Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
622	+	+	-	-	624	+	-	-	-
617	+	+	-	-	618	-	-	-	-
623	-	+	-	-	620	-	-	-	-
664	+	+	+	+	625	-	-	-	+
668	+	+	-	+	665	-	+	-	-
986	-	+	-	-	670	-	-	-	-
610	-	+	-	+	675	-	-	-	-
611	-	-	-	-	995	-	+	-	-
612	-	-	-	-	606	+	-	-	-
615	+	+	-	+	607	-	-	-	-
616	-	+	-	+	613	-	-	-	+
990	-	-	-	+	614	-	-	-	-
994	-	-	-	-	991	-	-	-	-
673	+	+	+	+	992	+	-	-	-
674	+	+	+	+	667	-	-	-	-
741	-	-	-	-	669	-	-	-	-
979	-	+	-	-	672	-	-	-	-
981	+	+	-	-	977	-	-	-	-
982	+	+	-	-	978	-	-	-	-
985	-	+	-	-	983	-	-	-	+
744	-	+	-	-	742	-	-	-	-
746	+	+	+	+	743	-	-	-	-
748	+	+	+	+	745	-	-	-	-
750	+	+	+	+	747	-	+	-	-
976	+	+	-	-	749	+	-	-	-

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae* (MH)
Study Purpose	Efficacy against respiratory disease caused by *Mycoplasma hyopneumoniae*
Product Administration	Two doses, administered intramuscularly, 3 weeks apart
Study Animals	MH serologically negative, commercial pigs, 3 days of age at first administration; 59 vaccinates and 56 controls.
Challenge Description	*Mycoplasma hyopneumoniae*, administered 3 weeks after second vaccination
Interval observed after challenge	Lungs were evaluated 4 weeks after challenge for the presence of *Mycoplasma hyopneumoniae*-specific lung lesions.
Results	The percent of the lung that was abnormal (consolidated) was calculated for every animal.

5-number summary for lung consolidation (%):

Treatment	Min	Q1	Median	Q3	Max
Controls	0.35	7.0	15.3	20.1	62.4
Vaccinates	0.05	2.7	7.9	14.1	54.8

Lung consolidation scores (%), in order of rank:

Vaccinates		Controls	
ID	**% Lung Consolidation**	**ID**	**% Lung Consolidation**
318	0.05	286	0.35
320	0.25	247	1.00
323	0.60	255	1.65
204	0.70	304	2.90
361	0.73	299	3.45
334	1.10	289	4.95
319	1.30	309	5.15
313	1.35	370	5.18
205	1.40	206	5.55
336	1.70	202	5.70
300	2.08	213	5.70
295	2.10	265	6.10
220	2.20	280	6.28
371	2.70	333	6.55

325	2.73	261	7.40
222	2.75	310	7.55
218	3.00	337	7.65
339	3.08	287	8.30
315	3.15	321	9.00
212	3.75	209	9.05
236	3.85	335	10.13
283	4.20	250	11.85
228	4.60	211	12.80
268	4.95	316	13.25
356	5.48	301	13.60
203	5.80	201	13.85
207	5.88	217	14.45
294	5.90	226	14.90
290	6.28	326	15.70
237	7.90	330	16.20
303	8.00	340	16.25
285	8.23	305	16.95
314	8.95	302	17.05
244	9.05	219	17.15
214	9.10	369	17.25
243	10.35	249	17.55
253	10.40	281	17.55
282	10.55	252	18.15
296	10.65	269	18.90
241	10.80	293	18.90
273	10.90	353	19.30
267	12.00	327	19.85
232	12.40	256	20.40
245	13.40	231	21.00
297	14.10	224	21.60
372	14.40	317	22.15
329	15.45	350	22.50
275	17.50	291	23.50
264	19.40	238	24.80

	366	19.65	266	24.95
	251	20.25	239	25.80
	274	22.60	230	26.25
	233	24.15	234	38.10
	279	24.60	278	38.50
	235	25.15	364	41.75
	262	26.90	365	62.35
	223	34.40		
	367	44.25		
	242	54.80		
USDA Approval Date	April 18, 2017			

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae* (MH)
Study Purpose	Efficacy against respiratory disease caused by *Mycoplasma hyopneumoniae*.
Product Administration	One dose administered intramuscularly.
Study Animals	MH serologically negative, commercial pigs, 3 weeks of age at administration; 29 vaccinates and 29 controls.
Challenge Description	*Mycoplasma hyopneumoniae*, administered 3 weeks after vaccination.
Interval observed after challenge	Lungs were evaluated 4 weeks after challenge for the presence of *Mycoplasma hyopneumoniae*-specific lung lesions.
Results	The percent of the lung that was abnormal (consolidated) was calculated for every animal.

5-Number Summary for Lung Consolidation (%):

Treatment	Min	Q1	Median	Q3	Max
Controls	4.4	7.5	13.2	18.0	26.3
Vaccinates	0	2.0	5.3	10.5	20.8

Lung Consolidation Scores (%), In Order of Rank:

Vaccinates		Controls	
ID	**% Lung Consolidation**	**ID**	**% Lung Consolidation**
272	0.0	216	4.4
234	0.5	242	4.7
271	0.5	240	5.3
277	0.6	223	5.4
251	0.8	235	6.8
207	0.9	239	6.9
226	0.9	219	7.2
256	2.0	264	7.5
245	2.1	270	8.5
224	2.2	267	9.7
215	3.3	268	10.1
275	4.5	258	11.5
250	5.2	278	11.8
203	5.3	253	13.0

	238	5.3	252	13.2
	246	6.0	225	13.7
	214	6.7	211	13.7
	217	8.1	273	14.0
	243	8.6	248	15.0
	230	9.8	227	16.9
	274	10.0	237	17.8
	261	10.5	257	18.0
	220	12.1	205	18.8
	247	14.0	244	19.0
	218	15.6	222	19.1
	255	16.0	209	21.0
	208	16.6	206	21.5
	249	19.2	228	22.0
	212	20.8	254	26.3
USDA Approval Date	October 26, 2016			

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopnuemoniae* (MH)
Study Purpose	23-week duration of immunity against respiratory disease caused by *Mycoplasma hyopneumoniae*.
Product Administration	One dose administered intramuscularly.
Study Animals	MH serologically negative, commercial pigs, 3 weeks of age at administration; 32 vaccinates and 34 controls.
Challenge Description	*Mycoplasma hyopneumoniae*, administered 23 weeks after vaccination.
Interval observed after challenge	Lungs were evaluated 4 weeks after challenge for the presence of *Mycoplasma hyopneumoniae*-specific lung lesions.
Results	The percent of the lung that was abnormal (consolidated) was calculated for every animal.

5-Number Summary for Lung Consolidation (%):

Treatment	Min	Q1	Median	Q3	Max
Controls	0	1.4	2.7	5.8	18.2
Vaccinates	0	0.5	1.8	3.8	8.6

Lung Consolidation Scores (%), In Order of Rank:

Vaccinates		Controls	
ID	**% Lung Consolidation**	**ID**	**% Lung Consolidation**
232	0.0	248	0.0
293	0.0	385	0.5
295	0.0	184	0.6
357	0.1	288	0.6
379	0.3	383	0.7
183	0.4	363	0.8
277	0.4	289	1.0
191	0.5	372	1.0
366	0.5	371	1.4
230	0.7	294	1.6
182	0.9	389	1.8
243	1.4	187	1.9
284	1.5	273	2.0
298	1.7	354	2.2

Results (continued)	384	1.8	189	2.3
	299	1.8	190	2.5
	356	1.8	227	2.7
	246	1.9	239	2.7
	279	1.9	358	2.8
	225	2.0	282	2.8
	376	2.1	374	3.0
	381	3.2	297	3.1
	359	3.3	377	3.9
	362	3.6	274	4.7
	360	4.0	364	5.5
	387	4.7	286	5.8
	301	5.1	235	6.3
	244	5.4	388	7.0
	231	6.3	355	8.1
	378	7.8	236	9.2
	281	8.5	386	9.8
	238	8.6	304	10.0
			237	11.5
			306	18.2
USDA Approval Date	October 03, 2016			

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae* (MH)
Study Purpose	Pivotal efficacy against respiratory disease caused by *Mycoplasma hyopneumoniae*.
Product Administration	Two doses administered intramuscularly 2 weeks apart.
Study Animals	MH serologically negative, commercial pigs, 21 days of age at first administration; 32 vaccinates and 31 controls.
Challenge Description	*Mycoplasma hyopneumoniae*, administered 3 weeks after second vaccination.
Interval observed after challenge	Lungs were evaluated 4 weeks after challenge for the presence of *Mycoplasma hyopneumoniae*-specific lung lesions.
Results	The percent of the lung that was abnormal (consolidated) for all lung lobes was calculated for every animal.

5-Number Summary for Lung Consolidation (%):

Treatment	Min	Q1	Median	Q3	Max
Controls	0	3.1	10.89	14.8	35.0
Vaccinates	0.1	0.3	0.6	2.0	33.3

Lung Consolidation Scores (%), In Order of Rank:

Vaccinates		Controls	
ID	% Lung Consolidation	ID	% Lung Consolidation
3265	0.10	3242	0.00
3295	0.10	3252	0.18
3293	0.18	3297	0.40
3232	0.20	3282	0.70
3241	0.25	3251	1.05
3243	0.25	3249	1.28
3221	0.30	3264	1.78
3250	0.33	3291	2.90
3224	0.35	3225	3.20
3284	0.35	3271	4.55
3214	0.40	3234	5.68
3290	0.40	3223	6.80
3247	0.45	3246	7.20
3269	0.45	3210	7.95
3248	0.48	3272	8.60
3267	0.55	3299	9.88

Results (continued)	3217	0.60	3286	10.25
	3219	0.65	3212	11.90
	3226	0.70	3213	12.20
	3270	0.70	3222	12.50
	3218	0.75	3235	13.50
	3294	0.98	3266	13.70
	3233	1.85	3227	14.25
	3230	1.95	3287	15.25
	3283	2.05	3216	16.20
	3231	2.45	3236	16.65
	3240	3.30	3229	19.00
	3253	4.00	3239	20.00
	3215	5.48	3289	27.50
	3288	8.30	3296	33.70
	3238	27.35	3245	35.00
	3292	33.25		
USDA Approval Date	September 27, 2013			

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	Two doses, administered intramuscularly 2 weeks apart.
Study Animals	Commercial pigs at three different geographical locations, 3 weeks of age at first administration; 602 vaccinates and 148 controls were enrolled.
Challenge Description	N/A
Interval observed after challenge	Animals were observed daily as a group and individually post vaccination(s) until three weeks after the final vaccination.
Results	All 3 sites were combined for this summary.

Number of Animals with Clinical Signs

	Abnormal γ	**Cough**	**Depression**	**Diarrhea**	**Thin**	**Other ****	**Death *****
Control	14 (10%)	0 (0%)	2 (1%)	4 (3%)	7 (5%)	6 (4%)	0 (0%)
Vaccinate	48 (8%)	0 (0%)	12 (2%)	17 (3%)	24 (4%)	14 (2%)	8 (1%)

γ If animals were marked "abnormal;" specific clinical observations were marked or described as "other."
**Rash, lame, greasy pig, unable to stand were classified as "other."
***Death affirmed by licensee to have cause other than vaccination.
Percent was rounded to the nearest whole number.

Number of Animals with Injection Site Reactions

	1st Vaccination	**2nd Vaccination**
Control	0 (0%)	0 (0%)
Vaccinate	2 (1%)	10 (2%)

Percent was rounded to the nearest whole number.
Reactions resolved within 3 days.

USDA Approval Date	September 27, 2013

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	One dose administered intramuscularly.
Study Animals	Commercial pigs at three different geographical locations, 3 weeks of age at administration; 158 controls and 632 vaccinates were enrolled.
Challenge Description	N/A
Interval observed after challenge	Animals were observed daily as a group and individually post vaccination(s) until three weeks after the final vaccination.
Results	All 3 sites were combined for this summary. **Number of Animals with Clinical Signs** **Number of Animals with Injection Site Reactions**
USDA Approval Date	June 14, 2013

Number of Animals with Clinical Signs

	Abnormal γ	Anorexia	Depression	Diarrhea	Dyspnea	Other **	Death ***
Control	20 (13%)	8 (5%)	3 (2%)	6 (4%)	2 (1%)	9 (6%)	0 (0%)
Vaccinate	108 (17%)	29 (5%)	13 (2%)	17 (3%)	3 (1%)	81 (13%)	2 (0%)

γ If animals were marked "abnormal;" specific clinical observations were marked or described as "other."
**Cough, thin, lameness, lethargy, rough coat, jowl abscess were classified as "other."
***Death affirmed by licensee to have cause other than vaccination.
Percent was rounded to the nearest whole number.

Number of Animals with Injection Site Reactions

	Animals Ever with Reaction
Control	0 (0%)
Vaccinate	7 (1%)

Percent was rounded to the nearest whole number.
Reactions resolved within 3 days.

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	One dose administered intramuscularly at 3 weeks of age or two doses administered intramuscularly 3 weeks apart with first dose at 3 days of age.
Study Animals	Commercial pigs at three different geographical locations, a total of 600 vaccinates (200 receiving one-dose and 400 receiving two-doses) and 150 non-treated controls (50 per site) were enrolled.
Challenge Description	N/A
Interval observed after challenge	Animals were observed daily as a group and individually post vaccination(s) until three weeks after the final vaccination.
Results	Site A – One dose administration Sites B & C –Two dose administration **Injection Site Reactions Ever Present (# of Animals (% of Animals))**

	Site A		**Site B +**		**Site C**	
	1st	**2nd**	**1st**	**2nd**	**1st**	**2nd**
Non-Treated Control	0	n/a	2 (4%)	8 (17%)	0	0
Vaccinate	0	n/a	11 (6%)	38 (20%)	0	2 (1%)

Injection site reactions ranged from 0.5 to 5.0 cm. Reactions resolved within 7 days of first vaccination and within 14 days of second vaccination.
Percent was rounded to the nearest whole number.
n/a = Not Applicable
+ All site B animals were dosed with an autogenous vaccine in the same targeted vaccination site prior to the 2nd dose. Some animals (non-treated controls and vaccinates) had injection site reactions at the site of vaccination prior to the 2nd dose. Therefore it is not clear if the injection site reactions were attributable to the test article at site B.

Observations Ever Present (# of Animals (% of Animals))

	Site A		Site B		Site C	
	Control	Vaccinate	Control	Vaccinate	Control	Vaccinate
None	38 (76)	166 (83)	40 (80)	144 (72)	37 (74)	146 (73)
Cough	2 (4)	4 (2)	1 (2)	4 (2)	.	.
Incoordination	3 (6)	6 (3)	.	.	.	.
Increased respiratory rate	8 (16)	16 (8)	.	.	.	2 (1)
Joint swelling	5 (10)	4 (2)	.	.	1 (2)	1 (1)
Lameness	5 (10)	16 (8)	1 (2)	3 (2)	1 (2)	3 (2)
Lethargy	3 (6)	7 (4)	1 (2)	6 (3)	1 (2)	8 (4)
Not eating	2 (4)	1 (1)	.	.	.	.
Swollen limb	2 (4)	1 (1)	.	.	.	.
Unthrifty	2 (4)	1 (1)	5 (10)	38 (19)	1 (2)	12 (6)
Central nervous system disorder	.	2 (1)	.	.	.	.
Depression	.	1 (1)	.	.	.	.
Other ear disorder	.	2 (1)	.	.	.	.
Abdominal cavity hernia	.	.	1 (2)	.	.	2 (1)
Abrasion	.	.	1 (2)	.	.	1 (1)
Diarrhea	.	.	3 (6)	17 (9)	6 (12)	22 (11)
Scar	.	.	1 (2)	6 (3)	.	.
Sore Eye	.	.	1 (2)	.	.	.
Claw / hoof / nail disorder	.	.	.	1 (1)	.	.
Dermatitis	.	.	.	.	1 (2)	1 (1)
Head tilt - neurological disorder	.	.	.	.	2 (4)	.
Infectious disease	.	.	.	.	1 (2)	3 (2)
Scour	.	.	.	.	7 (14)	25 (13)
Fracture	.	.	.	.	.	1 (1)
Paraplegia	.	.	.	.	.	1 (1)
Weakness	.	.	.	.	.	1 (1)
Found Dead*	1 (2)	2 (1)	.	.	1 (2)	11 (6)
Death by Euthanasia*	.	.	2 (4)	9 (5)	.	2 (1)
Uncoded Sign	.	.	.	.	.	1 (1)

All observations were VeDDRA coded (Veterinary Dictionary for Drug Related Affairs).
Percent was rounded to the nearest whole number.
* All deaths were affirmed by Investigators to NOT be attributable to the product.

USDA Approval Date	November 1, 2017