Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19K5.R0
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac CircoFlex - Agritech Enterprise Sdn. Bhd. Ingelvac CircoFlex - Boehringer Ingelheim (Canada) Ltd. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health (Thai) Ltd. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health Australia Pty. Ltd. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health Canada Inc. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health Korea, Ltd. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health Mexico Ingelvac CircoFlex - Boehringer Ingelheim Animal Health New Zealand Ltd Ingelvac CircoFlex - Boehringer Ingelheim Animal Health Philippines, Inc. Ingelvac CircoFlex - Boehringer Ingelheim Animal Health South Africa (Pty) Ltd/ (Edms) Bpk Ingelvac CircoFlex - Boehringer Ingelheim Animal Health do Brasil Ltda Ingelvac CircoFlex - Boehringer Ingelheim India Pvt Ltd Ingelvac CircoFlex - Boehringer Ingelheim S.A. Ingelvac CircoFlex - Boehringer Ingelheim Serbia d.o.o. Beograd Ingelvac CircoFlex - Boehringer Ingelheim Vetmedica GmbH Ingelvac CircoFlex - INSUVECA Ingelvac CircoFlex - No distributor specified Ingelvac CircoFlex - PT Boehringer Ingelheim Indonesia
Date of Compilation Summary	December 02, 2020

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	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Study Purpose	Demonstration of efficacy
Product Administration	Single intramuscular administration of vaccine. ORF2 gene of strain PCV2a.
Study Animals	Caesarian-derived, colostrum deprived pigs vaccinated at 23-25 days of age and randomly divided into 24 vaccinates and 24 controls
Challenge Description	All pigs were challenged 14 days following vaccination with Porcine Circovirus, Type 2a challenge virus.
Interval observed after challenge	Lymphoid tissues were examined 25 days after challenge.
Results	**Summary of Lymphoid Tissue Efficacy Results**

Group & Treatment	Lymphoid Depletion +/total (%)	Lymphoid Inflammation +/total (%)	Lymphoid IHC +/total (%)
PCV2 Vaccine	3/24 (12.5%)	3/24 (12.5%)	3/24 (12.5%)
Control Article	17/24 (70.8%)	18/24 (75%)	19/24 (79.2%)

Raw Data Tables of Positive Lymphoid Tissue by Parameter and Tissue

IHC = Immunohistochemistry
MLN = Mesenteric Lymph Node
ILN = Iliac Lymph Node
TBLN = Tracheobronchial Lymph Node

Lymphoid Depletion Criteria:
Negative (-) = No lymphoid depletion present
Positive (+) = Lymphoid depletion to some degree present

Lymphoid Inflammation Criteria:
Negative (-) = No lymphoid inflammation present
Positive (+) = Lymphoid inflammation to some degree present

Lymphoid IHC Criteria:
Negative (-) = Zero lymphoid cells with PCV2 antigen
Positive (+) = PCV2 antigen detected in lymphoid cells

Raw data is presented on the following pages.

USDA Approval Date	June 28, 2007

Vaccinated pigs:

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
5	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-	-	-	-
37	-	-	-	+	-	-	+	+	-	-	-	+
38	-	-	-	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-	-	-	-
50	-	-	+	-	+	+	+	+	+	-	+	-
85	-	-	-	-	-	-	-	-	-	-	-	-
87	-	-	-	-	-	-	-	-	-	-	-	-
88	-	-	-	-	-	-	-	-	-	-	-	-
89	-	-	-	-	-	-	-	-	-	-	-	-
90	-	-	-	-	-	-	-	-	-	-	-	-
91	-	-	-	-	-	-	-	-	-	-	-	-
92	-	+	+	+	+	+	+	+	+	-	-	+
94	-	-	-	-	-	-	-	-	-	-	-	-

Control Pigs

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
1	-	-	-	-	-	-	-	-	+	-	-	-
2	-	-	+	-	-	+	+	+	-	+	+	+
4	+	+	+	+	+	+	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	+	-	-	-	+	+	-	-	+	-
11	-	-	-	-	-	-	-	-	-	-	-	-
13	+	+	+	+	+	+	+	+	+	+	+	+
15	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-
19	-	+	+	+	+	+	+	+	-	+	+	+
22	-	-	-	-	-	-	-	-	-	-	-	-
25	-	+	+	+	+	+	+	+	+	+	+	+
26	-	-	-	+	+	-	+	+	-	-	-	+
28	-	-	+	+	-	+	+	+	-	+	+	+
32	+	+	+	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	-	+	+	+
34	+	+	+	+	+	+	+	+	+	+	+	+
35	-	-	+	+	+	-	+	+	-	-	-	+
39	-	+	+	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+	+	+	+
44	-	-	+	+	+	+	+	+	+	-	+	+
45	+	+	+	+	+	+	+	+	+	+	+	+
48	-	-	+	-	-	-	+	+	-	-	+	-
86	-	-	-	-	-	+	-	-	-	-	+	-

Study Type	Efficacy
Pertaining to	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Study Purpose	Demonstration of efficacy
Product Administration	Single intramuscular administration of vaccine. ORF2 gene of strain PCV2a.
Study Animals	Caesarian-derived, colostrum deprived pigs vaccinated at 17 – 26 days of age and randomly divided into 22 vaccinates and 22 controls
Challenge Description	All pigs were challenged 32 days following vaccination with Porcine Circovirus, Type 2a challenge virus.
Interval observed after challenge	Lymphoid tissues were examined 25 days after challenge.

Results

Summary of Efficacy Results

Group & Treatment	Lymphoid Depletion +/total * (%)	Lymphoid Inflammation +/total * (%)	Lymphoid IHC +/total * (%)
Vaccinates	0/21 (0%)	0/21 (0%)	3/21 (14.3%)
Controls	16/21 (76.2%)	18/21 (85.7%)	21/21 (100%)

Observations of Tissues by Parameter and Tissue
IHC = Immunohistochemistry
MLN = Mesenteric Lymph Node
ILN = Iliac Lymph Node
TBLN = Tracheobronchial Lymph Node

Lymphoid Depletion Criteria:
Negative (-) = Normal, no lymphoid depletion present
Positive (+) = Mild, moderate or severe depletion

Lymphoid Inflammation Criteria:
Negative (-) = Normal, no lymphoid inflammation
Positive (+) = Mild, moderate or severe histiocytic to granulomatous inflammation

Lymphoid IHC Criteria:
Negative (-) = Zero lymphoid cells with PCV2 antigen staining
Positive (+) = Lymphoid follicles have cells with PCV2 antigen staining

	Raw data is presented on the following pages.
USDA Approval Date	April 10, 2006

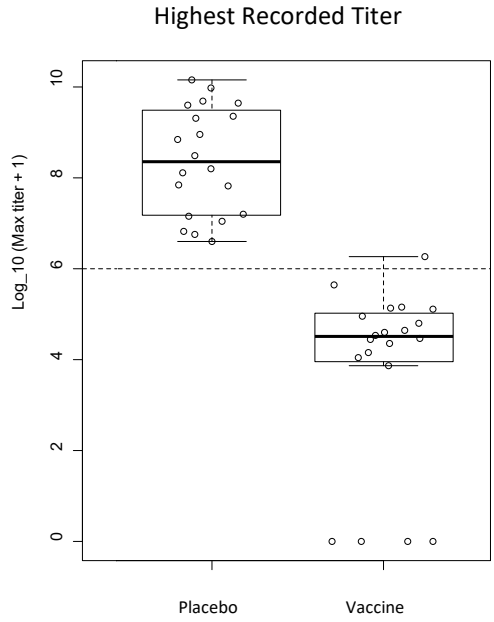
Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
	Vaccinates											
17	-	-	-	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	+	-	-	-
50	-	-	-	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-	-	-	-
61	-	-	-	-	-	-	-	-	-	-	-	-
62	-	-	-	-	-	-	-	-	-	-	-	-
63	-	-	-	-	-	-	-	-	-	-	-	-
80	-	-	-	-	-	-	-	-	-	-	-	-
84	-	-	-	-	-	-	-	-	-	-	-	-
86	-	-	-	-	-	-	-	-	+	-	-	-
87	-	-	-	-	-	-	-	-	-	-	-	-
91	-	-	-	-	-	-	-	-	-	-	-	-
115	-	-	-	-	-	-	-	-	+	-	-	-
124	-	-	-	-	-	-	-	-	-	-	-	-
173	-	-	-	-	-	-	-	-	-	-	-	-

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
	Controls											
5	-	-	-	+	-	-	-	+	+	-	+	+
6	-	-	-	+	-	-	-	+	+	-	-	+
9	-	-	-	-	-	-	-	-	+	-	-	+
20	-	-	-	+	-	-	-	+	+	-	-	+
28	-	+	+	+	+	+	+	+	+	+	+	+
30	-	+	+	+	+	+	+	+	+	+	+	+
38	-	-	-	-	-	-	-	-	+	+	+	+
40	-	-	-	+	-	-	-	+	+	+	+	+
52	-	-	-	+	+	+	+	+	+	+	+	+
55	-	-	-	+	+	-	-	+	-	+	-	+
57	-	-	-	-	+	-	-	-	-	+	-	-
58	+	+	+	+	+	+	+	+	+	+	+	+
65	+	-	-	+	+	+	+	+	+	+	+	+
67	-	-	-	+	-	-	-	+	+	+	+	+
68	-	+	-	+	-	+	-	+	+	+	+	+
71	+	-	-	+	+	+	+	+	+	+	+	+
81	-	-	+	+	-	+	+	+	+	+	+	+
83	-	-	-	+	+	-	+	+	+	+	+	+
93	-	-	-	-	-	-	-	+	+	+	+	+
125	-	+	+	+	-	+	+	+	+	+	+	+
175	-	-	-	-	-	-	-	-	+	+	+	+

Study Type	Efficacy
Pertaining to	Porcine Circovirus Type 2 (PCV2)
Study Purpose	Demonstration of efficacy against PCV2
Product Administration	Single intramuscular administration of vaccine. Product tested contained ORF2 gene of strain PCV2a.
Study Animals	Caesarian-derived, colostrum deprived pigs vaccinated at 22 days of age and randomly divided into 20 vaccinates and 20 controls
Challenge Description	All pigs were challenged with Porcine Circovirus, Type 2 challenge virus 17 days following vaccination .
Interval observed after challenge	Blood collected at Days 17 (day of challenge), 24, 31, 38 and 42 and tested for the presence of PCV2. Lymphoid tissues were examined 25 days after challenge.
Results	**Summary of Lymphoid Tissue Results**

Group & Treatment	**Lymphoid Depletion +/total (%)**	**Lymphoid Inflammation +/total (%)**	**Lymphoid IHC +/total (%)**
PCV2 Vaccine	1/20 (5%)	9/20 (45%)	5/20 (25%)
Control Article	15/20 (76%)	20/20 (100%)	20/20 (100%)

Postchallenge Viremia (virus in blood)
Magnitude of each pig's highest titer**:**



Raw Data Tables: Lymphoid Tissue Evaluation

IHC = Immunohistochemistry
MLN = Mesenteric Lymph Node
ILN = Iliac Lymph Node
TBLN = Tracheobronchial Lymph Node

Lymphoid Depletion Criteria:
Negative (-) = No lymphoid depletion present
Positive (+) = Lymphoid depletion to some degree present

Lymphoid Inflammation Criteria:
Negative (-) = No lymphoid inflammation present
Positive (+) = Lymphoid inflammation to some degree present

Lymphoid IHC Criteria:
Negative (-) = Zero lymphoid cells with PCV2 antigen
Positive (+) = PCV2 antigen detected in lymphoid cells

Vaccinated Pigs

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
1	-	-	-	-	+	+	-	-	+	-	-	-
13	-	-	-	-	-	+	-	+	+	+	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	+	-	-	-	-	-	-
32	-	-	-	-	-	+	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-	-	-	-
39	-	+	-	-	+	+	+	+	+	+	-	+
42	-	-	-	-	-	-	-	+	-	-	-	-
48	-	-	-	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	+	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-	-	-	-
67	-	-	-	-	-	-	-	-	-	-	-	-
68	-	-	-	-	-	-	-	-	-	-	-	-
79	-	-	-	-	-	-	-	-	-	-	-	-
83	-	-	-	-	-	-	-	-	-	-	-	-
87	-	-	-	-	-	+	-	+	+	-	-	-
88	-	-	-	-	-	-	-	-	-	-	-	-
93	-	-	-	-	-	+	-	+	-	+	-	+
100	-	-	-	-	-	-	-	-	-	-	-	-

Control Pigs

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
4	+	+	+	+	+	+	+	+	+	+	+	+
12	-	-	-	-	-	-	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+	+	+	+
18	-	+	-	-	+	+	+	+	+	+	+	+
21	-	+	-	-	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+	+	+	+
47	-	+	-	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+	+	+	+
60	-	-	-	-	-	+	-	+	-	-	-	+
62	-	+	-	+	+	+	+	+	-	+	+	+
70	-	-	-	-	-	+	+	-	-	+	+	-
72	+	+	+	+	+	+	+	+	+	+	+	+
73	-	+	-	-	+	+	+	+	-	+	+	+
77	-	-	-	-	+	+	+	+	-	+	+	+
80	+	+	+	+	+	+	+	+	+	+	+	+
89	+	+	+	+	+	+	+	+	+	+	+	+
95	-	-	-	-	-	+	-	-	-	+	-	-
99	+	+	+	+	+	+	+	+	+	+	+	+
110	+	+	+	+	+	+	+	+	+	+	+	+

Raw Data Tables: Viremia
Vaccinated Pigs

Pig ID	Day 17	Day 24	Day 31	Day 38	Day 42
1	0.000E+00	8.972E+04	0.000E+00	1.397E+05	0.000E+00
13	0.000E+00	4.063E+04	2.968E+04	0.000E+00	0.000E+00
14	0.000E+00	0.000E+00	0.000E+00	1.910E+06	0.000E+00
20	0.000E+00	0.000E+00	0.000E+00	0.000E+00	0.000E+00
27	0.000E+00	0.000E+00	3.526E+04	1.004E+04	0.000E+00
32	0.000E+00	0.000E+00	2.354E+04	1.211E+04	0.000E+00
36	0.000E+00	3.468E+04	6.430E+03	1.108E+04	4.428E+05
39	0.000E+00	2.875E+04	5.791E+03	0.000E+00	7.167E+03
42	0.000E+00	0.000E+00	0.000E+00	0.000E+00	0.000E+00
48	0.000E+00	1.909E+04	2.954E+04	8.086E+03	0.000E+00
50	0.000E+00	0.000E+00	0.000E+00	0.000E+00	0.000E+00
54	0.000E+00	0.000E+00	0.000E+00	0.000E+00	7.578E+03
67	0.000E+00	0.000E+00	0.000E+00	0.000E+00	0.000E+00
68	0.000E+00	1.369E+04	1.826E+04	1.287E+05	2.158E+04
79	0.000E+00	2.525E+04	9.273E+04	7.833E+03	0.000E+00
83	0.000E+00	6.333E+04	0.000E+00	0.000E+00	0.000E+00
87	0.000E+00	1.995E+04	4.518E+04	1.079E+04	0.000E+00
88	0.000E+00	1.149E+04	9.302E+03	0.000E+00	0.000E+00
93	0.000E+00	1.420E+05	2.218E+04	6.908E+03	0.000E+00
100	0.000E+00	0.000E+00	1.450E+04	0.000E+00	0.000E+00

Control Pigs

Pig ID	Day 17	Day 24	Day 31	Day 38	Day 42
4	0.000E+00	6.937E+06	3.791E+08	2.339E+09	1.082E+09
12	0.000E+00	4.554E+07	2.451E+07	6.808E+07	2.149E+06
17	0.000E+00	1.191E+07	4.103E+08	7.280E+08	.
18	0.000E+00	1.272E+05	2.418E+05	1.305E+08	2.244E+05
21	0.000E+00	1.261E+06	6.719E+06	1.817E+06	3.333E+06
29	0.000E+00	3.738E+06	1.394E+09	4.940E+09	.
41	0.000E+00	1.435E+06	2.912E+08	5.548E+09	1.498E+10
47	0.000E+00	8.045E+04	3.244E+06	1.120E+07	9.013E+06
51	0.000E+00	3.217E+06	8.720E+07	4.151E+09	1.327E+09
60	0.000E+00	2.081E+06	3.023E+06	3.845E+06	4.027E+06
62	0.000E+00	1.483E+05	8.530E+05	1.015E+07	1.649E+08
70	0.000E+00	5.824E+05	3.346E+05	5.945E+06	2.385E+06
72	0.000E+00	1.603E+07	2.959E+08	1.888E+09	9.877E+09
73	0.000E+00	1.463E+07	1.636E+07	1.209E+07	5.360E+06
77	0.000E+00	5.786E+05	3.407E+07	7.208E+07	1.025E+07
80	0.000E+00	5.511E+06	3.173E+08	2.501E+08	.
89	0.000E+00	1.040E+06	3.725E+08	2.139E+09	.
95	0.000E+00	1.810E+05	1.454E+07	1.957E+06	2.226E+06
99	0.000E+00	9.251E+06	5.557E+08	4.276E+08	4.503E+09
110	0.000E+00	3.884E+06	4.197E+06	4.032E+08	9.355E+08

"." = Missing Data

USDA Approval Date	December 2, 2010

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of 4 months duration of immunity</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine. ORF2 gene of strain PCV2a.</td></tr>
<tr><td>Study Animals</td><td>Caesarian-derived colostrum deprived pigs vaccinated at 19 – 23 days of age and randomly divided into 24 vaccinates and 24 controls</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 122 days (4months) following vaccination with Porcine Circovirus, Type 2a challenge virus.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lymphoid tissues were examined 25 days after challenge.</td></tr>
<tr><td>Results</td><td>Summary of Efficacy Results
<table>
<tr><th>Group & Treatment</th><th>Lymphoid Depletion +/total (%)</th><th>Lymphoid Inflammation +/total (%)</th><th>Lymphoid IHC +/total (%)</th></tr>
<tr><td>Group # 1 – PCV2 Vaccine</td><td>0/24 (0%)</td><td>0/24 (0%)</td><td>0/24 (0%)</td></tr>
<tr><td>Group # 2 - Control Group</td><td>13/24 (54.2%)</td><td>20/24 (83.3%)</td><td>20/24 (83.3%)</td></tr>
</table>
Observations of Lymphoid Tissue by Parameter and Tissue:
IHC = Immunohistochemistry
MLN = Mesenteric Lymph Node
ILN = Iliac Lymph Node
TBLN = Tracheobronchial Lymph Node

Lymphoid Depletion Criteria:
Negative (-) = Normal, no lymphoid depletion present
Positive (+) = Mild, moderate or severe depletion

Lymphoid Inflammation Criteria:
Negative (-) = Normal, no lymphoid inflammation
Positive (+) = Mild, moderate or severe histiocytic to granulomatous inflammation

Lymphoid IHC Criteria:
Negative (-) = Zero lymphoid cells observed with PCV2 antigen staining
Positive (+) = Lymphoid follicles have cells with PCV2 antigen staining

Raw data is presented on the following pages.</td></tr>
</table>

USDA Approval Date	April 17, 2007

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILM	TBLN	Tonsil	MLN	ILN	TBLN
	Group 1: PCV2 Vaccine											
5	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-	-	-	-
59	-	-	-	-	-	-	-	-	-	-	-	-
66	-	-	-	-	-	-	-	-	-	-	-	-
68	-	-	-	-	-	-	-	-	-	-	-	-
71	-	-	-	-	-	-	-	-	-	-	-	-
80	-	-	-	-	-	-	-	-	-	-	-	-
83	-	-	-	-	-	-	-	-	-	-	-	-
89	-	-	-	-	-	-	-	-	-	-	-	-
99	-	-	-	-	-	-	-	-	-	-	-	-
109	-	-	-	-	-	-	-	-	-	-	-	-
113	-	-	-	-	-	-	-	-	-	-	-	-
114	-	-	-	-	-	-	-	-	-	-	-	-
119	-	-	-	-	-	-	-	-	-	-	-	-

Pig ID	Lymphoid Depletion				Lymphoid Inflammation				Lymphoid IHC			
	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN	Tonsil	MLN	ILN	TBLN
	Group 2: Control Group											
1	+	-	+	+	+	+	+	+	+	+	+	+
7	+	-	+	+	+	+	+	+	+	+	+	+
9	-	-	+	-	+	+	+	-	+	-	+	-
13	-	-	-	-	+	-	+	-	-	-	+	-
28	-	-	-	+	+	-	+	+	-	-	-	+
29	-	-	-	-	+	-	-	-	+	-	-	-

31	-	+	+	+	+	+	+	+	+	+	+	+
35	+	+	-	+	+	+	+	+	+	+	+	+
40	+	-	+	+	+	+	+	+	+	+	+	+
41	-	-	-	-	+	+	+	+	+	-	+	+
46	-	-	-	-	-	-	-	-	-	-	-	-
51	+	-	-	-	+	+	-	+	+	+	+	+
60	-	-	+	-	+	+	+	-	+	+	+	-
69	-	-	+	-	+	+	+	-	+	+	+	-
74	-	-	-	+	+	+	-	+	+	-	-	+
75	-	-	-	-	-	-	-	-	-	-	-	-
92	+	-	-	-	+	-	+	+	+	-	-	+
93	-	-	-	-	+	-	-	+	+	-	-	-
98	-	-	-	-	-	-	-	-	-	-	-	-
100	-	-	-	-	+	-	-	-	+	-	-	-
104	-	+	-	-	+	+	+	-	+	+	+	-
110	-	-	-	-	+	-	-	-	+	-	-	-
116	-	-	-	-	+	-	-	-	+	-	-	-
117	-	-	-	-	-	-	-	-	-	-	-	-

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration</td></tr>
<tr><td>Study Animals</td><td>1355 pigs at 10 - 30 days of age, (≥200 pigs from each of three different geographical locations were vaccinated, and a similar number at each site were not vaccinated for comparison)</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed immediately following vaccination and then for 14 days following vaccination. No challenge was conducted.</td></tr>
<tr><td>Results</td><td>Observations of Vaccinated Pigs:
<table>
<tr><th>Clinical Observation [a]</th><th>MO Site N=244</th><th>NE Site N=229</th><th>IN Site N=207</th></tr>
<tr><td>None [b]</td><td>241</td><td>210</td><td>193</td></tr>
<tr><td>Poor Condition [c]</td><td>0</td><td>15</td><td>0</td></tr>
<tr><td>Dead [d]</td><td>3</td><td>2</td><td>3</td></tr>
<tr><td>Scours</td><td>0</td><td>1</td><td>10</td></tr>
<tr><td>Lame</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>Swollen Joint(s)</td><td>2</td><td>0</td><td>0</td></tr>
<tr><td>Cough</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>Skin Abnormalities [e]</td><td>0</td><td>1</td><td>1</td></tr>
</table>
[a] Pigs may have exhibited more than one clinical observation.
[b] For an observation of “None” a pig had to be without clinical observations for the entire 14 days of the study.
[c] Observations of “Poor Condition” included: thin starve, small thin, small, gaunt, gaunt weak, and thin.
[d] Observation of “Dead” included: Dead, Died, and Euthanized.
[e] Observation of “Skin Abnormalities” included: scabbed knees and skin spots</td></tr>
</table>

Observations of **Control** Pigs:

Clinical Observation [a]	**MO Site N=241**	**NE Site N=228**	**IN Site N=206**
None [b]	**237**	**209**	**195**
Poor Condition [c]	0	13	0
Dead [d]	4	2	1
Scours	0	0	9
Lame [e]	0	3	1
Swollen Joint(s)	2	0	0
Hernia [f]	0	2	0

[a] Pigs may have exhibited more than one clinical observation.
[b] For an observation of "None" a pig had to be without clinical observations for the entire 14 days of the study.
[c] Observations of "Poor Condition" included: thin, gaunt, gaunt/weak, and gaunt-purple ears.
[d] Observation of "Dead" included: dead, died, and euthanized.
[e] Observation of "Lame" included: lame, sore right front foot, and shoulder
[f] Observation of "Hernia" included: hernia and surgery.

USDA Approval Date	April 5, 2006