Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2799.20
True Name	Lawsonia Intracellularis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Porcilis Ileitis - Intervet Argentina S.A. Porcilis Ileitis - Intervet Chile Ltda - Merck Sharpe and Dohme (MSD) Porcilis Ileitis - Intervet Veterinaria Chile Ltda Porcilis Ileitis - MSD Animal Health Porcilis Ileitis - MSD Salud Animal Columbia S.A.S. Porcilis Ileitis - MSD Salud Animal Columbia S.A.S. - Merck Sharpe and Dohme (MSD) Porcilis Ileitis - Merck Animal Health Porcilis Ileitis - Merck Sharp & Dohme Saude Animal Ltda. Porcilis Ileitis - No distributor specified
Date of Compilation Summary	December 11, 2021

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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Lawsonia intracellularis</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against ileitis</td></tr>
<tr><td>Product Administration</td><td>A single 2 mL dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>37 vaccinate and 37 control pigs, 3-4 weeks of age
Group A: 23 vaccinates and 23 placebo controls
Group B: 14 vaccinates and 14 placebo controls</td></tr>
<tr><td>Challenge Description</td><td>Lawsonia intracellularis administered 4 weeks following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Group A: For Ileitis and Colonization, tissues were evaluated 21 days post-challenge
Group B: For Shedding, feces were evaluated three times a week for up to 60 days post-challenge</td></tr>
<tr><td>Results</td><td><u>Ileitis</u>
Group A animals were considered affected by the challenge if they presented with a gross lesion score > 1 or a microscopic histopathological lesion score > 0.
<table>
<tr><td rowspan="2">Treatment Group</td><td colspan="2">Gross Lesion Score >1</td><td rowspan="2">Histopathological Lesion Score >0</td><td rowspan="2">Affected</td></tr>
<tr><td>Scorer #1</td><td>Scorer #2</td></tr>
<tr><td>Vaccinate</td><td>12/23</td><td>11/23</td><td>8/23</td><td>14/23</td></tr>
<tr><td>Control</td><td>13/23</td><td>14/23</td><td>22/23</td><td>23/23</td></tr>
</table>
<u>Colonization</u>
Group A animals were considered affected if they presented with a microscopic immunohistochemistry (IHC) score of > 0 or a qPCR value ≥ limit of detection (LOD) for Lawsonia in mucosal scrapings.
<table>
<tr><td>Treatment Group</td><td>Affected</td></tr>
<tr><td>Vaccinate</td><td>10/23</td></tr>
<tr><td>Control</td><td>23/23</td></tr>
</table>
<u>Fecal Shedding</u>
Group B animals were considered affected if they presented with a qPCR value ≥ LOD for Lawsonia in fecal samples for one or more of the post-challenge testing time points. Summary for duration of shedding in days is as follows:</td></tr>
</table>

	<table><tr><th>Treatment</th><th>Min</th><th>Q_1</th><th>Median</th><th>Q_3</th><th>Max</th></tr><tr><td>Controls</td><td>8</td><td>19</td><td>22</td><td>29</td><td>31</td></tr><tr><td>Vaccinates</td><td>0</td><td>8</td><td>12</td><td>19</td><td>29</td></tr></table> Raw data are shown below.
USDA Approval Date	March 5, 2014

SCORING GUIDE

Ileitis

Gross Lesion Score
0 – Normal mucosa
1 – Slight mucosal edema or slight hyperemia
2 – Moderate ileitis
3 – Severe ileitis
4 – Severe ileitis plus additionally hemorrhaging and/or necrosis, blood clots or yellowish pseudomembrane

Microscopic Histopathological Lesion Score
0 No diagnostic lesions
1 Mild individual crypt proliferative change
2 Marked proliferative enterocolitis

Colonization

IHC Score
0 Negative, no staining
1 Positive, rare positive staining in fewer than 10 crypts per section
2 Positive, moderate positive staining in 10-20 crypts per section
3 Positive, abundant positive staining in more than 20 crypts per section

qPCR of Mucosal Scrapings
Results shown are Log_{10} DNA copies/reaction
BLD: Below Limit of Detection

Fecal Shedding

qPCR of Fecal Samples
Results shown are Log_{10} DNA copies/reaction
B: Below Limit of Detection
ns: No Sample

RAW DATA TABLES

Vaccinate Group A					
ID	Gross Lesion Scores		Histopathological Score	IHC Score	qPCR of Mucosal Scrapings
	Scorer #1	Scorer #2			
86	0	0	0	0	BLD
90	2	2	0	0	1.5
91	1	1	0	0	BLD
92	2	3	0	0	BLD
96	1	1	1	1	2.5
102	0	0	0	0	BLD
103	2	1	0	0	BLD
104	2	2	0	0	BLD
105	1	1	0	0	BLD
108	2	2	2	3	2.0
110	2	2	1	2	2.8
118	1	1	0	0	0.8
127	2	2	1	2	2.2
132	1	1	2	3	1.6
133	2	2	1	2	2.9
136	1	1	0	0	BLD
140	2	2	0	0	BLD
141	2	2	0	0	BLD
149	1	1	0	0	BLD
151	2	2	2	3	3.9
155	1	1	0	0	BLD
156	1	1	0	0	BLD
161	2	2	1	1	2.2

Control Group A					
ID	Gross Lesion Scores		Histopathological Score	IHC Score	qPCR of Mucosal Scrapings
	Scorer #1	Scorer #2			
85	1	1	1	2	3.3
87	1	1	1	1	2.3
89	2	2	0	0	0.9
95	1	2	1	1	2.2
98	1	1	2	3	4.1
99	2	2	1	2	3.1
100	3	3	2	3	3.7
107	2	2	2	3	3.0
112	1	1	2	3	2.6
113	3	3	2	3	3.5
114	3	3	2	3	3.3
120	0	0	2	3	2.1
122	4	4	2	3	2.0
124	2	2	1	1	1.2
128	1	1	1	1	2.2
134	0	0	1	1	2.6
137	1	1	1	1	2.1
143	1	1	1	1	2.2
145	2	2	2	3	4.5
152	2	2	1	1	2.8
157	3	3	2	3	3.8
160	2	2	1	1	3.1
163	4	4	2	3	4.1

Fecal Shedding Group B

		Day Post-Challenge																									
ID	Treatment	-3	4	6	8	11	13	15	18	20	22	25	27	29	32	34	36	39	41	43	46	48	50	53	55	57	60
84	Vaccinate	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
88	Vaccinate	B	B	B	B	B	B	1.4	3.0	ns	3.3	3.2	2.8	1.7	1.2	B	B	B	B	0.7	B	B	B	B	B	B	B
94	Vaccinate	B	B	B	B	B	B	B	B	B	B	0.8	1.1	1.1	B	B	B	B	B	B	B	B	B	B	B	B	B
106	Vaccinate	B	B	B	B	B	0.7	0.6	1.7	1.1	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
111	Vaccinate	B	B	B	B	B	B	B	0.6	1.0	1.1	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
121	Vaccinate	B	B	B	0.6	0.5	0.9	2.0	3.1	2.7	1.3	B	0.5	B	B	B	B	B	B	B	B	B	B	B	B	B	B
123	Vaccinate	B	B	B	B	B	B	B	1.8	1.8	1.0	B	0.7	B	B	B	B	B	B	B	B	B	B	B	B	B	B
130	Vaccinate	B	B	B	B	B	B	B	1.6	2.4	2.5	2.8	3.2	3.7	3.5	3.6	3.3	3.6	3.6	3.4	3.3	2.9	3.4	3.5	3.1	2.5	1.5
131	Vaccinate	B	B	B	B	1.1	1.2	2.1	2.6	2.8	2.2	2.5	2.5	2.7	2.1	1.5	0.7	B	B	B	B	B	B	B	B	B	B
138	Vaccinate	B	B	B	B	B	B	B	B	0.9	B	B	0.9	0.5	0.5	1.0	B	B	B	B	B	B	B	B	B	B	B
150	Vaccinate	B	B	B	B	B	B	B	2.3	2.9	1.0	3.4	2.1	1.2	B	B	B	B	B	B	B	B	B	B	B	B	B
153	Vaccinate	B	B	B	B	B	B	1.2	2.1	1.5	1.5	B	0.9	B	B	B	B	B	B	B	B	B	B	B	B	B	B
162	Vaccinate	B	B	B	B	0.6	0.6	1.0	4.4	3.3	2.8	1.5	B	0.5	B	B	B	B	B	B	B	B	B	B	B	B	B
165	Vaccinate	B	B	B	B	0.7	0.6	1.1	2.4	1.5	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
82	Control	B	B	B	B	B	B	B	1.4	1.8	1.8	1.5	0.9	B	B	B	B	B	B	0.9	0.9	B	B	B	B	B	B
83	Control	B	B	B	B	B	0.8	2.0	3.5	3.1	1.4	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
93	Control	B	B	B	1.0	2.7	3.4	4.6																			
109	Control	B	B	B	B	2.0	3.1	3.5	4.5	4.1	2.8	2.1	2.1	1.7	B	B	B	B	B	B	B	B	B	B	B	B	B
115	Control	B	B	B	0.6	2.0	2.0	2.4	4.0	4.2	3.7	2.0	1.2	0.5	B	B	B	B	B	B	B	B	B	B	ns	B	B
116	Control	B	B	B	B	B	B	1.3	2.2	1.9	1.3	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
119	Control	B	B	B	B	1.4	2.6	3.8	3.8	3.7	3.7	1.5	1.4	0.8	B	B	B	B	B	B	B	B	B	B	B	B	B
125	Control	B	B	B	B	1.5	1.7	2.7	4.6	5.1	4.6	4.4	4.0	2.5	3.7	B	B	B	0.6	B	B	B	B	B	B	B	B
126	Control	B	B	0.9	2.2	2.6	2.8	4.5	5.1	5.5	5.0	3.6	3.7	4.1	1.1	3.1	1.9	B	B	B	B	B	B	B	B	B	B
129	Control	B	B	B	B	1.4	1.7	2.5	5.2	5.5	5.0	4.5	4.0	2.1	2.4	4.2	4.3	2.0	B	B	B	B	B	B	B	B	B
144	Control	B	B	B	B	1.0	1.5	2.6	4.1	4.0	3.4	3.1	3.1	2.7	2.3	1.8	B	B	B	B	B	B	B	B	B	B	B
146	Control	B	B	B	B	0.5	B	1.0	1.6	2.5	2.7	1.4	1.5	0.8	B	B	B	B	B	B	B	B	B	B	B	B	B
148	Control	B	B	B	B	B	B	ns	1.6	B	1.0	2.3	2.1	0.8	B	B	B	B	B	B	B	B	B	B	B	B	B
154	Control	B	B	B	0.9	1.7	2.9	3.6	2.2	4.9	4.3	3.5	3.0	1.5	B	B	B	B	B	B	B	B	B	B	B	B	B

The firm affirmed that ID 93 died as a result of the challenge.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Lawsonia intracellularis</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 20-week duration of immunity against ileitis</td></tr>
<tr><td>Product Administration</td><td>A single 2 mL dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>38 vaccinate and 40 control pigs, 3-4 weeks of age
Group A: 24 vaccinates and 25 placebo controls
Group B: 14 vaccinates and 15 placebo controls</td></tr>
<tr><td>Challenge Description</td><td>Lawsonia intracellularis administered 20 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Group A: For Ileitis and Colonization, tissues were evaluated 21 days post-challenge
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<tr><td>Results</td><td><u>Ileitis</u>
Group A animals were considered affected by the challenge if they presented with a gross lesion score > 1 or a microscopic histopathological lesion score > 0.
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<tr><td rowspan="2">Treatment Group</td><td colspan="2">Gross Lesion Score >1</td><td rowspan="2">Histopathological Lesion Score >0</td><td rowspan="2">Affected</td></tr>
<tr><td>Scorer #1</td><td>Scorer #2</td></tr>
<tr><td>Vaccinate</td><td>5/24</td><td>5/24</td><td>5/24</td><td>5/24</td></tr>
<tr><td>Control</td><td>15/25</td><td>16/25</td><td>19/25</td><td>19/25</td></tr>
</table>
<u>Colonization</u>
Group A animals were considered affected if they presented with a microscopic immunohistochemistry (IHC) score of > 0 or a qPCR value ≥ limit of detection (LOD) for Lawsonia in mucosal scrapings.
<table>
<tr><td>Treatment Group</td><td>Affected</td></tr>
<tr><td>Vaccinate</td><td>13/24</td></tr>
<tr><td>Control</td><td>23/25</td></tr>
</table>
<u>Fecal Shedding</u>
Group B animals were considered affected if they presented a qPCR value ≥ LOD for Lawsonia in fecal samples for one or more of the post challenge testing time points. Samples were collected every 2-3 days. Summary for duration of shedding in days is as follows:</td></tr>
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	<table><tr><td>Treatment</td><td>Min</td><td>Q_1</td><td>Median</td><td>Q_3</td><td>Max</td></tr><tr><td>Controls</td><td>10</td><td>17</td><td>19</td><td>21</td><td>36</td></tr><tr><td>Vaccinates</td><td>0</td><td>5</td><td>7</td><td>12</td><td>25</td></tr></table> Raw data shown below
USDA Approval Date	March 6, 2014

SCORING GUIDE

Ileitis

Gross Lesion Score
0 – Normal mucosa
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IHC Score
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qPCR of Mucosal Scrapings
Results shown are Log_{10} DNA copies/reaction
BLD: Below Limit Of Detection

Fecal Shedding

qPCR of Fecal Samples

Results shown are Log_{10} DNA copies/reaction
B: Below Limit Of Detection

RAW DATA TABLES

Vaccinate Group A					
ID	Gross Lesion Scores		Histopathological Score	IHC Score	qPCR of Mucosal Scrapings
	Scorer #1	Scorer #2			
629	1	1	0	0	0.5
634	1	1	0	0	1.2
638	1	1	0	0	BLD
639	1	1	0	0	BLD
641	1	1	0	0	BLD
645	0	0	0	0	1.0
648	0	0	0	0	1.0
653	0	1	0	0	1.7
655	1	1	0	0	BLD
659	1	1	0	0	BLD
663	0	0	0	0	BLD
665	2	2	0	0	0.7
670	0	0	0	0	1.8
673	1	1	0	0	BLD
674	0	0	0	0	BLD
675	1	0	0	0	BLD
676	1	1	0	0	0.7
681	2	2	2	2	3.5
683	2	2	0	0	0.7
684	2	3	2	3	3.5
691	1	1	0	0	0.7
698	2	3	0	0	BLD
699	1	1	0	0	BLD
707	1	1	0	0	1.4

Control Group A					
ID	Gross Lesion Scores		Histopathological Score	IHC Score	qPCR of Mucosal Scrapings
	Scorer #1	Scorer #2			
631	2	2	2	3	3.9
632	4	4	2	3	5.0
633	3	3	2	3	4.1
637	1	2	2	3	4.0
643	3	3	2	3	2.1
649	2	3	2	3	4.0
651	2	2	2	2	3.3
652	1	0	2	2	1.0
654	3	3	2	2	2.2
661	0	0	0	0	1.1
662	1	1	0	0	0.5
668	4	4	2	2	3.6
669	3	3	2	3	3.7
671	0	0	0	0	1.5
678	3	3	2	2	3.9
679	1	1	2	3	1.1
685	2	2	2	3	2.8
686	1	1	0	0	BLD
687	0	0	0	0	0.7
689	4	4	2	2	3.2
694	1	1	1	1	1.1
696	3	3	2	3	3.0
701	1	1	0	0	BLD
706	2	2	1	1	2.8
709	2	2	1	1	2.1

Fecal Shedding Group B

ID	Treatment	Day Post-Challenge																								
		-3	2	4	7	9	11	14	16	18	21	23	25	28	30	32	35	37	39	42	44	46	49
630	Vaccinate	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
640	Vaccinate	B	B	B	2.4	2.5	2.5	2.6	2.1	3.3	2.6	0.6	B	B	B	B	B	B	B	B	B	B	B	B	B	B
644	Vaccinate	B	B	B	B	B	1.4	1.7	0.8	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
646	Vaccinate	B	B	B	B	1.9	2.4	0.9	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
656	Vaccinate	B	B	B	B	1.3	2.3	2.9	2.3	1.4	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
664	Vaccinate	B	B	B	B	1.2	2.0	2.6	0.9	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
672	Vaccinate	B	B	0.9	1.9	2.2	1.8	1.2	B	B	B	B	0.6	1.0	B	B	B	B	B	B	B	B	B	B	B	B
677	Vaccinate	B	B	1.3	2.7	3.4	3.9	4.5	4.3	4.1	3.0	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
688	Vaccinate	B	B	B	0.7	0.9	1.1	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
692	Vaccinate	B	B	B	0.9	1.1	1.0	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
700	Vaccinate	B	B	B	B	B	B	1.9	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
703	Vaccinate	B	B	B	B	B	B	B	0.7	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
704	Vaccinate	B	B	B	1.9	1.8	2.0	3.1	3.2	1.4	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
708	Vaccinate	B	B	B	0.9	2.1	3.1	1.9	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
628	Control	B	B	B	B	1.5	1.5	1.9	2.1	2.5	2.6	1.9	1.8	B	B	B	B	B	B	B	B	B	B	B	B	B
642	Control	B	B	B	0.7	2.0	3.0	3.5	3.6	3.2	2.4	1.8	B	B	B	B	B	B	B	B	B	B	B	B	B	B
647	Control	B	B	B	B	1.0	1.5	2.5	3.2	3.3	3.3	2.9	2.6	1.2	B	B	B	B	B	B	B	B	B	B	B	B
650	Control	B	B	B	B	B	1.6	2.2	2.7	2.7	3.2	2.4	2.2	2.3	1.4	B	B	B	B	B	B	B	B	B	B	B
657	Control	B	B	B	0.5	0.9	1.8	1.8	1.7	0.6	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
660	Control	B	B	B	0.7	1.8	2.7	3.6	3.5	3.6	2.9	1.1	B	B	B	B	B	B	B	B	B	B	B	B	B	B
667	Control	B	B	B	1.9	2.3	3.9	5.0	5.2	4.3	5.7	4.8	5.0	3.7	3.8	3.6	3.2	3.8	2.6	0.5	B	B	B	B	B	B
680	Control	B	B	B	1.4	1.2	3.3	4.2	4.1	4.2	4.7	4.5	4.7	4.0	3.0	B	B	0.6	B	B	B	B	B	B	B	B
682	Control	B	B	1.1	1.4	2.6	2.8	3.1	2.7	2.5	2.1	1.8	1.4	B	B	B	B	B	B	B	B	B	B	B	B	B
693	Control	B	B	B	B	1.2	1.7	1.9	2.2	1.0	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
695	Control	B	B	B	1.9	2.3	3.3	4.8	5.2	4.3	2.7	3.0	1.5	B	B	B	B	B	B	B	B	B	B	B	B	B
697	Control	B	B	B	1.2	2.8	3.1	4.8	4.5	4.5	4.5	3.6	0.6	B	B	B	B	B	B	B	B	B	B	B	B	B
702	Control	B	B	1.2	1.9	2.2	3.7	3.7	2.9	2.2	1.7	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
705	Control	B	B	0.7	2.3	2.9	4.0	5.7	5.4	5.2	4.9	3.2	0.6	B	B	B	B	B	B	B	B	B	B	B	B	B
711	Control	B	B	B	1.5	2.0	2.7	3.7	3.7	3.3	3.3	1.8	1.6	B	B	B	B	B	B	B	B	B	B	B	B	B

<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>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>1,220 pigs, 17-31 days of age, at five study sites in three geographically distinct locations.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed once between one and four hours after vaccination, and then daily for 14 days, or until resolution of any adverse events.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Adverse Events (AE)
(Total 1,220 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Swelling[1] *

S (<1.5 cm)
M (1.5 to 5 cm)
L (>5 to 10 cm)</td><td>453

291
148
14</td></tr>
<tr><td>Anaphylactic-type reaction*</td><td>24</td></tr>
<tr><td>Systemic disorder NOS[2]</td><td>22</td></tr>
<tr><td>Death by euthanasia (Septicemia)</td><td>6</td></tr>
<tr><td>Scour</td><td>4</td></tr>
<tr><td>Found dead (Septicemia)</td><td>3</td></tr>
<tr><td>Death by euthanasia (Systemic disorder NOS)</td><td>2</td></tr>
<tr><td>Lameness</td><td>2</td></tr>
<tr><td>Meningitis</td><td>2</td></tr>
<tr><td>Ataxia</td><td>1</td></tr>
<tr><td>Death (Anaphylactic-type reaction)*</td><td>1</td></tr>
<tr><td>Death by euthanasia (Hernia NOS)</td><td>1</td></tr>
<tr><td>Death by euthanasia (Meningitis)</td><td>1</td></tr>
<tr><td>Found dead (Bronchopneumonia)</td><td>1</td></tr>
<tr><td>Found dead (Systemic disorder NOS)</td><td>1</td></tr>
</table>
*Vaccine related AE.
[1]Injection site swellings resolved within 1- 19 days.
[2]Pigs that failed to achieve performance in the barn equal to that of their contemporaries, and included pigs defined as lethargic, rough haired, depressed, thin, gaunt, off feed, unthriftness, anorexia, starve-out.
NOS = Not otherwise specified
</td></tr>
<tr><td>USDA Approval Date</td><td>July 31, 2015</td></tr>
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