

# **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4585.22
True Name	Bovine Rotavirus-Coronavirus Vaccine, Killed Virus, Escherichia Coli Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Scourguard 4K - No distributor specified Scourguard 4K - Zoetis Hayvan Sagligi Ltd Scourguard 4K - Zoetis Korea Scourguard 4K - Zoetis New Zealand Ltd Ultravac Scourshield - Zoetis Australia Pty Ltd
Date of Compilation Summary	February 25, 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.

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Study Type	Efficacy
Pertaining to	Bovine Coronavirus (BCV)
Study Purpose	Demonstrate passive immunity against diarrhea caused by BCV
	in calves
<b>Product Administration</b>	2 doses of vaccine administered intramuscularly (IM)
	approximately 6 and 3 weeks prior to calving.
Study Animals	Thirty-eight (38) neonatal calves (0 to 6 hours of age) were
	removed from their dams prior to first nursing and were fed
	colostrum/milk from pre-assigned heifers that had been
	vaccinated previously with the vaccine $(n = 18)$ or with a
	placebo ( $n = 20$ ).
Challenge Description	BCV administered at 8 to 12 hours of age to calves
Interval observed after	Calves were observed up to 10 days post-challenge for clinical
challenge	signs and mortality.
Results	Mortality rate and clinical scores for fecal consistency, attitude, appetite, and dehydration for BCV disease were calculated. Fecal scores ≥ 1, attitude score ≥ 1, appetite score ≥ 1 and dehydration score ≥ 1 were considered abnormal.  Mortality: Calves fed colostrum/milk from pre-assigned heifers that had been vaccinated previously with a placebo: 13/20 (65.0%)  Calves fed colostrum/milk from pre-assigned heifers that had been vaccinated previously with the vaccine: 2/18 (11.1%)  See the following tables for individual raw data.
USDA Approval Date	08/27/2003

### **Fecal Consistency Scoring:**

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					Days of o	bservatio	on post-c	hallenge*	ė		
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0/0	0/0	0 / 0	0/0	1 / 1	1 / 1	0/0	2/2	2/2	1 / 1
SI	04	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	-	-	-	-
a m	05	0 / 0	0/0	0 / 0	0 / 0	2/2	2/2	2/2	2/2	1 / 1	0 / 0
	07	0 / 0	0/0	0 / 0	0 / 0	0 / 0	1 / 1	1 / 1	2/2	2/2	1 / 1
<u> </u>	09	0/0	1 / 1	0 / 0	0 / 0	1 / 1	0 / 0	2/2	2/2	0/0	0/0
nt	11	0 / 0	0/0	1 / 1	0 / 0	1 / 1	2/2	2/2	2/2	2/2	2/2
၂ ပိ	13	0 / 0	1 / 1	0/0	0 / 0	2/2	1 / 1	2/2	2/2	1 / 1	1 / 1
lε	16	0/0	1 / 1	0/0	-	-	-	-	-	-	-
Calves Fed Colostrum from Control Dams	17	0/0	1 / 1	0/0	1 / 1	2/2	2/2	-	-	-	-
n f	20	0 / 0	0/0	ı	-	-	-	-	-	-	-
] ii	22	0/0	0/0	0 / 0	0/0	0/0	1 / 1	2/2	2/2	-	-
str	23	0 / 0	2/2	2/2	2/2	2 /2	2/2	-	-	-	-
ရ	25	0 / 0	2/2	0 / 0	0 / 0	0/0	2/2	2/2	2/-	-	-
Ŭ	28	0 / 0	2/2	1 / 1	1 / 1	0 / 0	0 / 0	0 / 0	1 / 1	2/2	-
eq	29	0 / 0	0/0	2/2	2/2	2/2	-	-	-	-	-
<u> </u>	32	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	2/-	-	-	-
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	33	0/0	1 / 1	0 / 0	0/0	0/0	2/2	2/2	2/2	2/2	2/2
[a]	36	0/0	0/0	0 / 1	0/0	0/0	2/2	1 / 1	-	-	-
	38	0/0	2/2	1 / 1	1 / 1	2/2	2/2	2 / -	-	-	-
	39	0/0	2/2	2/2	1 / 1	2/2	2/2	2/2	-	-	-
l _	01	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	2/2	1 / 1	1 / 1	0/0
ted	03	0/0	0/0	0 / 0	0/0	0/0	0/0	2/2	1 / 1	1 / 1	0/0
na	06	0/0	0/0	0 / 0	0 / 0	0/0	0 / 0	1 / 1	0/0	0 / 0	0/0
]	08	0/0	0/0	0 / 0	0 / 0	0/0	0 / 0	0/0	0/0	0/0	0/0
/ <b>a</b> /	10	0/0	2/2	1 / 1	0/0	0/0	0/0	0/0	2/2	2/2	2/2
from Vaccinated	12	0/0	0/0	0 / 0	0/0	1 / 1	2/2	2/2	2/2	-	-
.o.	14	0/0	2/2	0/0	0/0	0/0	2/2	2/2	2/2	2/2	2/2
_ 7	15	0/0	2/2	0/0	0/0	0/0	0/0	2/2	1/1	-	-
strum Dams	18	0/0	1/1	0/0	0/0	0/0	0/0	0/0	2/2	1/1	1/1
D. St.	19	0/0	1/1	0/0	0/0	0/0	1/1	2/2	1/1	1/1	1/1
Calves Fed Colostrum Dam	21	0/0	0/0	0/0	0/0	0/0	0/0	2/2	1/1	0/0	0/0
ŭ	24	0/0	2/2	0/0	0/0	0/0	2/2	2/2	2/2	1/1	1/1
þa	26	0/0	0/0	0/0	0/0	0/0	0/0	1/1	2/2	2/2	2/2
Ĕ	27	0/0	2/2	0/0	0/0	0/0	0/0	2/2	2/2	2/2	2/2
/es	31	0/0	0/0	0/0	0/0	0/0	0/0	2/2	2/2	2/2	1/1
a l	35	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
$\mathcal{C}$	37	0/0	0/0	0/0	0/0	2/2	2/2	2/2	1/1	1/1	2/2
	40	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1	1 / 1

#### **Appetite Scoring:**

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
-= Animal no longer on study
Fecal Scores: 0 = Normal; 1, 2 = Abnormal

		Days o	f observat	tion post-	challeng	e*					
Treatment Group	Animal ID	0 AM/P M <sup>#</sup>	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
S	04	0 / 1	2/2	1/2	1/2	1/2	1 / 1	-	-	-	-
an	05	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0/0
	07	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0/0
ro L	09	0/0	0 / 0	0/0	0/0	0/0	0 / 0	0/0	0/0	0/0	0/0
nt	11	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	2/0	0 / 0	0 / 0	1/2
Calves Fed Colostrum from Control Dams	13	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0/0
	16	0 / 0	1/0	0/0	-	-	-	-	-	-	-
	17	0 / 0	0 / 0	0/0	0 / 0	0 / 0	2/2	-	-	-	-
l f	20	0/2	2/2	-	-	-	-	-	-	-	-
E	22	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	-	-
str	23	0/2	1 / 1	0/0	0/0	0/0	0 / 2	-	-	-	-
<b> </b>	25	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	2/-	-	-
ŭ	28	0/0	0 / 1	0 / 1	0 / 0	0/0	0 / 0	0 / 0	0 / 1	2/2	-
pa	29	0/0	0 / 0	0/0	0 / 0	0/2	-	-	-	-	-
<u> </u>	32	0/0	0 / 1	0/0	0 / 0	0 / 0	0 / 0	0 / -	-	-	-
ves	33	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	2/2
्रह	36	0/0	1/0	1 / 1	1 / 1	0 / 0	0 / 0	0 / 2	-	-	-
$\circ$	38	0/0	0 / 1	0/0	0 / 0	0 / 0	0 / 0	2 / -	-	-	-
	39	0/0	0 / 0	0 / 1	0 / 0	0 / 0	0 / 0	2/2	-	-	-
	01	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
ed	03	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0 / 0	0/0	0 / 0	0/0
ıat	06	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
cir	08	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
)ac	10	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0
	12	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0/0	2/2	-	-
from Vaccinated	14	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	1/2
of the second	15	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	-	-
strum Dam	18	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0/0	0 / 0	0 / 0	0/0
tr Da	19	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0/0
SO	21	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0/0
Calves Fed Colostrum Dame	24	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0
д (	26	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
Fe	27	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
es	31	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
اِجَ	35	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
Ű	37	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1 / 0	0 / 0	0 / 0	0 / 0
	40	0 / 0	0 / 0	0/0	0 / 0	0/0	0 / 0	0/0	0 / 0	0/0	0/0

#### **Attitude Scoring:**

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Appetite Scores: 0 = Normal; 1, 2 = Abnormal

		Days of	observat	ion post-	challeng	e*					
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0 / 0	0 / **	0 / 0	0 / 0	0 / 1	0 / 0	0/0	1/2	1/1	0 / 1
JS	04	0 / 1	2/0	2/2	2/2	1/2	2/2	3 / -	-	-	-
an	05	0/0	0/0	0/0	0/0	0 / 1	1 / 1	1/2	1/2	1/1	0 / 1
$\Box$	07	0/0	0/0	0 / 0	1 / 1	0 / 0	0 / 0	0 / 1	1/2	1/2	0 / 1
ro	09	0/0	0/0	0/0	0/0	0/0	0 / 0	1/2	1/2	0 / 0	0 / 0
nt	11	0/0	0 / 1	0 / 1	0/0	0 / 1	1/2	2/2	1/2	2/2	2/2
Calves Fed Colostrum from Control Dams	13	0/0	0/0	0 / 1	0 / 1	1/2	0 / 1	1 / 1	1/2	1/1	2/2
	16	0/0	1 /1	0 / 1	-	-	-	-	-	-	-
ro ro	17	0 / 0	1 / 1	0 / 1	2/2	2/2	2/3	-	-	-	-
l n	20	0 / 1	2/3	-	-	-	-	-	-	-	-
E	22	0/0	0 / 1	0 / 0	0 / 0	0 / 1	0 / 1	0 / 1	1/2	-	-
stı	23	0 / 0	1/2	0 / 1	1 / 1	1/2	2/2	-	-	-	-
1 원	25	0/0	0 / 1	0 / 1	0 / 0	0 / 1	1/2	1/2	3 / -	-	-
Ŭ	28	0 / 1	1/2	1 / 2	1/2	0 / 1	0 / 0	1 / 1	1 / 1	2/3	-
eq	29	0/0	0 / 0	1 / 1	1 / 2	2/2	-	-	-	-	-
<b>X</b>	32	0/0	0 / 1	0 / 0	0 / 1	0/0	0/0	2/-	-	-	-
\ e	33	0/0	1 / 2	0 / 0	0 / 0	0/0	0 / 1	1 / 1	2/2	2/2	2/3
<b>[R</b> ]	36	0/0	1 / 1	1 / 2	0 / 1	0 / 1	1 / 1	2/3	-	-	-
	38	0/0	1/2	1 / 1	0 / 1	1 / 1	1 / 2	3 / -	-	-	-
	39	0 / 0	0 / 1	2/2	1 / 1	1 / 1	2/2	2/3	-	-	-
l _	01	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	0 / 0	0 / 0	0 / 0
ted	03	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	1/2	0 / 1	1 / 1	0 / 0
แล	06	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0
[izi	08	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	
/ <b>a</b> C	10	0/0	1 / 2	0 / 1	0 / 1	0 / 0	0/0	0/0	1/2	0 / 1	1 / 1
	12	0/0	0/0	0 / 0	0 / 0	0 / 1	1 / 1	1 / 2	2/3	-	-
from Vaccinated	14	0/0	1/2	0 / 1	0/0	0/0	1 / 1	1/2	0 / 1	2/2	2/2
_ 7	15	0/0	1 / 1	0 / 0	0/0	0/0	0/0	1/2	0 / 1	-	-
strum Dam	18	0/0	1/1	0/0	0/0	0/0	0/0	0 / 1	1 / 2	0/0	0/0
itri Da	19	0/0	0 / 1	0 / 0	0/0	0 / 1	1 / 1	1 / 2	0/0	1 / 1	1 / 1
los	21	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	0/0	1/2	0 / 1
Calves Fed Colostrum Dame	24	0/0	1/1	0/0	0/0	0/0	1/1	2/2	2/2	1/1	1/1
g	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/2	1/1	1/2
Fe	27	0/0	0 / 1	0/0	0/0	0/0	0/0	0 / 1	1/2	1/1	1/1
es	31	0/0	0/0	0/0	0/0	0/0	0/0	1/1	1/2	1/1	0/0
aly	35	0/0	0/1	0 / 1	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Ü	37	0/0	0/0	0/0	0/0	1/2	1/2	2/2	1/1	1/1	2/2
	40	0/0	0/0	0 / 0	0/0	0/0	0 / 0	0/0	0/0	0 / 0	1 / 1

#### **Dehydration Scoring:**

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)

\*\* = Datapoint not available
- = Animal no longer on study
Attitude Scores: 0 = Normal; 1, 2, 3 = Abnormal

		Days of	observat	ion post-	challeng	e*					
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0/0	0 / 0	0/0	0/0	0 / 1	0 / 0	0 / 0	1/2	1 / 1	0 / 1
SI	04	0/0	2/2	1/2	2/2	1/2	2/2	-	-	-	-
an	05	0/0	0/0	0/0	0 / 0	0 / 1	1 / 1	1/2	1/2	1 / 1	0 / 1
D	07	0/0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 1	1/2	1/2	0 / 1
[5]	09	0/0	0/0	0/0	0 / 0	0 / 0	0 / 0	1/2	1/2	0 / 0	0 / 0
Calves Fed Colostrum from Control Dams	11	0 / 0	0/0	0 / 1	0 / 0	0 / 1	1/2	2/2	1 / 2	2/2	2/2
ပိ	13	0 / 0	0/0	0 / 1	0 / 1	1/2	0 / 1	1 / 1	1 / 2	1 / 1	2/2
<b>E</b>	16	0/0	1 / 1	0 / 1	-	-	-	-	-	-	-
ro]	17	0/0	1 / 1	0 / 1	2/2	2/2	2/3	-	-	-	-
n f	20	0/0	2/3	-	-	-	-	-	-	-	-
_ in.	22	0/0	0 / 1	0/0	0 / 0	0 / 1	0 / 1	0 / 1	1 / 2	-	-
str	23	0/0	1 / 2	0 / 1	1 / 1	1/2	2/2	-	-	-	-
olo	25	0/0	0 / 1	0 / 1	0 / 0	0 / 1	1/2	1/2	3 / -	-	-
Ŭ	28	0/0	1 / 2	1/2	1/2	0 / 1	0 / 0	1 / 1	1 / 1	2/3	-
eq	29	0/0	0 / 0	1 / 1	1/2	2/2	-	-	-	-	-
<b>X</b>	32	0/0	0 / 1	0/0	0 / 1	0 / 0	0 / 0	2 / -	-	-	-
ves	33	0/0	1 / 2	0/0	0 / 0	0/0	0 / 1	1 / 1	2/2	2/2	2/3
[a]	36	0/0	1 / 1	1/2	0 / 1	0 / 1	1/2	2/3	-	-	-
$\sim$	38	0/0	1 / 2	1 / 1	0 / 1	1 / 1	1/2	3 / -	-	-	-
	39	0/0	0 / 1	2/2	1 / 1	1 / 1	2/2	2/3	-	-	-
	01	0/0	0 / 0	0/0	0/0	0 / 0	0 / 0	1 / 1	0 / 0	0 / 0	0/0
l ed	03	0/0	0 / 0	0/0	0/0	0 / 0	0 / 0	1/2	0 / 1	1/1	0 / 0
กสา	06	0/0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
Ċ.	08	0/0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
from Vaccinated	10	0/0	1 / 1	0 / 1	0 / 1	0/0	0/0	0/0	1/2	0 / 1	1 / 1
\ u	12	0/0	0 / 0	0/0	0 / 0	0 / 1	1 / 1	1/2	2/3	-	-
u 0.	14	0/0	1 / 1	0 / 1	0 / 0	0 / 0	1 / 1	1/2	0 / 1	2/2	2/2
n fi	15	0/0	1 / 1	0/0	0/0	0/0	0/0	1/2	0 / 1	-	-
trum Dam	18	0/0	1 / 1	0/0	0/0	0/0	0/0	0 / 1	1/2	0/0	0/0
itri Da	19	0/0	0 / 1	0/0	0 / 0	0 / 1	1 / 1	1/2	0/0	1 / 1	1 / 1
los	21	0/0	0 / 0	0/0	0/0	0/0	0/0	0 / 1	0/0	1 / 1	0 / 1
၂၁	24	0/0	1/1	0/0	0/0	0/0	1/1	2/2	2/2	1/1	1/1
Calves Fed Colostrum Dams	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/2	1/1	1/2
Fe	27	0/0	0 / 1	0/0	0/0	0/0	0/0	0 / 1	1/2	1/1	1/1
es	31	0/0	0/0	0/0	0/0	0/0	0/0	1/1	1/2	1/1	1/1
a v	35	0/0	0 / 1	0 / 1	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Ü	37	0/0	0/0	0/0	0/0	1/2	1/2	2/2	1/1	1/1	2/2
	40	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	1 / 1

#### Mortality (Yes / No)

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<sup>\*</sup>Day 0 = day of challenge # Animals were scored in the AM and PM (Score recorded as AM / PM)

<sup>- =</sup> Animal no longer on study Dehydration Scores: 0 = Normal; 1, 2, 3 = Abnormal

nent up	al ID	Mortality	y (Yes/No)
Treatment Group	Animal ID	Yes	No
	02		X
	04	X	
	05		X
	07		X
	09		X
	11		X
	13		X
Calara Ead	16	X	
Calves Fed	17	X	
Colostrum from Control	20	X X X X X X X X	
Dams	22	X	
Dailis	23	X	
	25	X	
	28	X	
	29	X	
	32	X	
	33		X
	36	X	
	38	X	
	39	X	
	01		X
	03		X X X
	06		X
	08		X
	10		X
	12	X	
Colves East	14		X
Calves Fed	15	X	
Colostrum from	18		X
Trom Vaccinated	19		X
V accinated Dams	21		X
Dains	24		X
	26		X
	27		X
	31		X
	35		X
	37		X
	40		X

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Study Type	Efficacy
Pertaining to	Escherichia coli K99 (E. coli K99)
Study Purpose	Demonstrate passive immunity against diarrhea caused by <i>E. coli</i> K99 in neonatal calves
<b>Product Administration</b>	2 doses of vaccine administered intramuscularly (IM) approximately 6 and 3 weeks to heifers prior to calving.
Study Animals	Twenty-eight (28) neonatal calves were removed from their dams prior to first nursing: 20 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with the vaccine; 8 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with a placebo (controls). Calves were negative for pre-colostral $E$ coli antibody titer ( $\leq$ 128).
Challenge Description	E coli administered orally at 8 to 12 hours of age to calves
Interval observed after	Calves were observed up to 6 days post-challenge for mortality
challenge	
Results	Mortality: Calves fed colostrum/milk from pre-assigned heifers that had been vaccinated previously with a placebo (controls): 8/8 (100.0%)  Calves fed colostrum/milk from pre-assigned heifers that had been vaccinated previously with the vaccine: 1/20 (5.0 %)  See tables for individual data.
<b>USDA Approval Date</b>	03/28/2005

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# **Mortality Results:**

T. 4 4 C	A ' 11D	Mortality	Yes / No
Treatment Group	Animal ID	YES	NO
	03	X	
	07	X	
	13	X	
Calves Fed Colostrum	17	X	
from Control Dams	24	X	
	26	X	
	30	X	
	37	X	
	01		X
	02		X
	06		X
	09		X
	10		X
	12		X
	14		X
	15		X
Colour Fold Coloratorium	18		X
Calves Fed Colostrum	19		X
from Vaccinated  Dams	20		X
Dams	21		X
	22	X	
	25		X
	28		X
	31		X
	32		X
	34		X
	36		X
	38		X

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Study Type	Efficacy
Pertaining to	Bovine Rotavirus serotype G10 (BRV G10)
Study Purpose	Demonstrate passive immunity against diarrhea caused by BRV G10 in calves
<b>Product Administration</b>	2 doses of vaccine administered intra muscularly (IM) approximately 6 and 3 weeks to pregnant heifers prior to calving.
Study Animals	Thirty-eight (38) neonatal calves were removed from their dams prior to first nursing; 20 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with the vaccine; 18 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with a placebo. Calves were negative for Pre-colostral virus neutralizing (VN) BRV antibody titer.
Challenge Description	BRV-2292B strain administered orally at 6 to 12 hours of age to calves
Interval observed after challenge	Calves were observed up to 9 days post-challenge for clinical signs and mortality.
Results	Calves were observed for fecal consistency, appetite, attitude, dehydration, and mortality.  See tables for individual data
<b>USDA Approval Date</b>	07/29/2004

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### **Fecal Consistency Scoring:**

					Davs of o	bservatio	on post-c	hallenge <sup>*</sup>	÷		Days of observation post-challenge*								
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #								
	02	0 / 0	1 / 1	1 / 1	2/2	2/2	2/2	2/2	2/2	2/2	1 / 1								
Ø	04	0/0	0 / 0	1 / 1	1/ 1	1 / 1	1 / 1	-	-	-	-								
am	08	0 / 0	1 / 1	0 / 0	1 / 1	0 / 0	0 / 0	1 / 1	1 / 1	0 / -	-								
ĺΩ̈́	09	0/0	0 / 0	2/2	2/2	2/2	2/2	2/2	2/2	0 / 1	1 / 1								
tro	12	0/0	0/0	0/0	0/0	1 / 1	1 / 1	1 / 1	1 / 1	1 / 1	1 / 1								
0 n1	13	0 / 0	0 / 0	2/2	1 / 1	0 / 0	1 / 1	0 / 0	2/2	1 / 1	1 / 1								
C	15	0 / 0	0 / 0	0 / 0	1 / 1	1 / 1	2/2	2/2	1 / 1	0 / 0	0 / 0								
mo.	18	0 / 0	0 / 0	2/2	0/0	0 / 0	1 / 1	1 / 1	0 / 0	1 / 1	0 / 0								
Calves fed colostrum from Control Dams	19	0 / 0	0 / 0	1 / 1	2/2	1 / 1	1 / 1	1 / 1	-	-	-								
_n,	22	0 / 0	0 / 0	1 / 1	1 / 1	0 / 0	1 / 1	1 / 1	1 / 1	1 / 1	2/2								
str	25	0 / 0	0 / 0	2/2	2/2	2/2	2/2	-	-	-	-								
colc	27	0 / 0	0 / 0	1 / 1	0/0	0/0	0 / 0	0/0	0 / 0	0 / 0	0/0								
d c	30	0 / 0	2/2	1 / 1	1 / 1	0/0	2/2	1 / 1	0 / 0	2/2	2/2								
s fe	32	0/0	0/0	1 / 1	0/0	0/0	0/0	0/0	0/0	1/1	2/2								
ve	33	0/0	0/0	0 / 0	0/0	0/0	1 / 1	1 / 1	1 / 1	1 / 1	0/0								
Ca	35	0/0	2/2	2/2	2/2	2/2	1/1	2/2	-	-	-								
	37	0 / 0	0/0	1/1	1/1	1/1	2/2	2/2	1/1	1/1	1 / 1								
	39	0 / 0	0 / 0	2/2	2/2	1 / 1	0 / 0	0 / 0	2/2	2/2	1 / 1								
	01	0/0	0/0	0/0	0/0	0/0	0/0	1/1	0/0	0/0	0/0								
	03	0/0	0/0	1 / 1	2/2	2/2	2/2	0/0	2/2	1/1	0/0								
	05	0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/2								
ms	07	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
Da	10	0 / 0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
eq	11	0/0	0/0	2/2	1/1	1/1	1/1	0/0	0/0	0/0	0/0								
nat	14	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
m Vaccinated Dams	16	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
Va	17	0/0	2/2	0/0	1/1	1/1	2/2	1/1	1/1	0/0	0/0								
	20	0/0	0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0	0/0								
fro	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
ш	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1								
tru	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
los	28	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1	1/1	1 /1								
Calves Fed Colostrum fro	29	0/0	0/0		1/1	0/0	0/0	1/1	1/1	1/1	2/2								
ed	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
S	34		2/2	0/0	1/1	0/0	0/0	1/1	2/2	0/0									
lve	36	0/0	0/0	0/0	0/0	0/0		0/0	0/0	0/0	0/0								
Ca	38	0/0	0/0	0/0	0/0	1/1	0/0	0/0	0/0	0/0	0/0								
	40	0 / 0	0 / 0	0 / 0	0/0	0/0	1 / 1	1 / 1	0 / 0	0 / 1	0 / 0								

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<sup>\*</sup>Day 0 = day of challenge # Animals were scored in the AM and PM (Score recorded as AM / PM) -= Animal no longer on study Fecal Scores: 0, 1 = Normal; 2 = Abnormal

### **Appetite Scoring:**

					Davs of o	bservatio	on post-c	hallenge <sup>*</sup>	÷		Days of observation post-challenge*								
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #								
	02	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1/0								
ø	04	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	-	-	-	-								
Calves fed colostrum from Control Dams	08	0 / 1	0 / 1	0 / 1	0 / 1	0 / 1	0 / 1	1/2	0 / 2	2 / -	-								
D	09	0 / 0	0 / 0	0 / 1	0 / 0	0 / 0	0 / 1	0 / 0	0 / 0	0 / 0	0 / 0								
rol	12	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
0 <b>ut</b>	13	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
Ċ	15	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0								
0 m	18	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
ı fr	19	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	2/2	-	-	-								
un	22	0 / 0	0 / 1	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 2	0 / 0								
str	25	0 / 0	0 / 1	0 / 0	0/0	0 / 0	2/2	-	-	-	-								
olo	27	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
d c	30	0 / 0	0 / 1	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
e fe	32	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
ves	33	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
Cal	35	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/2	-	-	-								
	37	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
	39	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
	01	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
	03	0 / 0	0 / 0	0 / 0	0 / 1	0/2	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
	05	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
ms	07	0 / 0	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0 / 0	0 / 0	0/0								
Dal	10	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
[ pa	11	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0								
late	14	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0/0	0 / 0	0 / 0	0/0								
m Vaccinated Dams	16	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0/0	0/0	0 / 0	0/0								
/aс	17	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0/0	0 / 0	0/0	0/0								
	20	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0								
[ro]	21	0/0	0 / 0	0/0	0/0	0/0	0 / 0	0/0	0/0	0/0	0/0								
l m	24	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
L.a	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
lost	28	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
Calves Fed Colostrum fro	29	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
pa	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
Ŧ	34	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
ve	36	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
	38	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0								
<u> </u>	40	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0								

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Appetite Scores: 0 = Normal; 1, 2 = Abnormal

### **Attitude Scoring:**

			Days of observation post-challenge*											
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #			
	02	0 / 1	1 / 2	1 / 2	2/2	1/2	1/2	2/2	2/2	2/2	2/2			
ø	04	0 / 0	0 / 0	1 / 1	0 / 1	0 / 1	1 / 1	-	-	-	-			
am	08	0 / 1	1 / 2	1 / 2	2/2	2/2	2 /2	2 /2	2 /2	2 / -	-			
D	09	0 / 0	0 / 0	0 / 1	0 / 0	1/2	1 / 1	2/2	2/2	2/2	1/2			
rol	12	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	1 / 1	2/2	1 / 1	1 / 1	1 / 1			
ont	13	0 / 0	0 / 0	1 / 2	0 / 1	0 / 0	0 / 0	0 / 0	1/2	1 / 1	0 / 1			
Č	15	0/0	0 / 0	0 / 0	1 / 1	0 / 1	1/2	1/2	1 / 1	0 / 0	0 / 0			
0 m	18	0 / 0	0 / 1	1 / 2	1 / 1	1 / 1	0 / 1	1 / 1	0 / 0	0 / 1	0 / 1			
Calves fed colostrum from Control Dams	19	0/0	0 / 0	1 / 1	1/2	1 / 1	2/2	2/2	-	-	-			
l un	22	0 / 0	0 / 0	0 / 1	0 / 1	0/0	0 / 1	1 / 1	0 / 0	0 / 1	2/2			
str	25	0 / 0	0 / 1	1 / 2	1 / 1	1/2	2/2	-	-	-	-			
olo	27	0/0	0 / 0	2/2	1/2	0 / 1	1 / 1	1 / 1	0 / 0	0 / 0	0 / 0			
d c	30	0/0	1 / 2	0 / 0	1/2	0 / 0	2/2	0 / 1	0 / 0	0 / 1	1 / 2			
e fe	32	0 / 0	0 / 0	1 / 1	0 / 1	1 / 1	0 / 0	0 / 0	0 / 0	0 / 1	1/2			
ves	33	0/0	0 / 0	0 / 0	0 / 1	0 / 0	0 / 1	0 / 0	0 / 1	0 / 0	0 / 0			
Cal	35	0 / 0	1 / 1	1 / 2	2/2	2/2	1/2	2/2	-	-	-			
	37	0 / 0	0 / 1	1 / 1	1/ 1	0/0	0 / 1	1/2	1/2	1/0	0 / 0			
	39	0 / 0	0 / 1	1 / 2	1 / 1	0 / 0	0 / 0	1 / 1	1/2	2 / 1	1 / 1			
	01	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0			
	03	0 / 1	0 / 0	0 / 0	0 / 1	0 / 1	2/2	0 / 0	1/2	1 / 1	1 / 1			
	05	0/0	1 / 1	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 1			
ms	07	0/0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0			
Da	10	0/0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0			
[ pa	11	0 / 0	0 / 0	0 / 1	0/0	0 / 0	1 / 1	1 / 1	0 / 0	0 / 0	0 / 0			
late	14	0 / 0	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0 / 0	0 / 0	0/0			
m Vaccinated Dams	16	0/0	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0/0	0 / 0	0/0			
/aс	17	0/0	0 / 1	0 / 0	0 / 1	0/0	0 / 1	1 / 1	0 / 1	0 / 0	0/0			
	20	0/0	0 / 0	0 / 0	0 / 1	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0			
[ro]	21	0/0	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0/0	0/0	0/0			
l m	24	0/0	0 / 0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1			
L.a	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
lost	28	0/0	0/0	0/0	0/0	0/0	0/0	1/1	0 / 1	1/1	0 / 1			
Calves Fed Colostrum fro	29	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	1/2			
pa	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
Ŧ	34	0/0	1/2	0/0	0/1	0/0	0/0	0/1	1/2	0 / 1	1/0			
ve	36	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
	38	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
<u> </u>	40	0/0	0 / 0	0 / 0	0/0	0/0	0 / 1	0 / 1	0 / 0	0 / 0	0 / 0			

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Attitude Scores: 0 = Normal; 1, 2, 3 = Abnormal

# **Dehydration Scoring:**

					Days of o	bservatio	on post-c	hallenge <sup>3</sup>	ŧ		
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0 / 0	1/2	1/2	2/2	1/2	1/2	2/2	2/2	2/2	2/2
ø	04	0 / 0	0/0	1 / 1	0 / 1	0 / 1	1 / 1	-	-	-	-
Calves fed colostrum from Control Dams	08	0 / 1	1/2	1/2	2/2	2/2	2/2	2/2	2/2	3 / -	-
Ê	09	0 / 0	0 / 0	0 / 1	0 / 0	1/2	1 / 1	2/2	2/2	2/2	1/2
rol	12	0 / 0	0 / 0	0/0	0/0	1 / 1	1 / 1	2/2	1 / 1	1 / 1	1 / 1
ont	13	0 / 0	0 / 0	1 / 2	0 / 1	0 / 0	0 / 0	0 / 0	1/2	1 / 1	0 / 1
Ö	15	0 / 0	0/0	0/0	1 / 1	0 / 1	1/2	1/2	1 / 1	0 / 0	0 / 0
O III	18	0 / 0	0 / 1	1 / 2	1 / 1	1 / 1	0 / 1	1 / 1	0 / 0	0 / 1	0 / 1
l fi	19	0 / 0	0 / 0	1 / 1	1/2	1 / 1	2/2	2/3	-	-	-
l m	22	0/0	0 / 0	0 / 1	0 / 1	0/0	0 / 1	1 / 1	0 / 0	0 / 1	2/2
str	25	0/0	0 / 1	1 / 2	1/ 1	1/2	2/3	-	-	-	-
olo	27	0/0	0 / 0	2/2	1/2	0 / 1	1 / 1	1 / 1	0 / 0	0 / 0	0 / 0
g c	30	0 / 0	1 / 2	0 / 0	1/2	0/0	2/2	0 / 1	0 / 0	0 / 1	1 / 2
e fe	32	0/0	0 / 0	1 / 1	0 / 1	1 / 1	0/0	0/0	0 / 0	0 / 1	1/2
ves	33	0/0	0 / 0	0 / 0	0 / 1	0/0	0 / 1	0 / 0	0 / 1	0 / 0	0 / 0
	35	0/0	1 / 1	1 / 2	2/2	2/2	1/2	2/3	-	-	-
	37	0 / 0	0 / 1	1 / 1	1 / 1	0/0	0 / 1	1/2	1 / 2	1/0	0/0
	39	0 / 0	0 / 1	1 / 2	1 / 1	0/0	0 / 0	1 / 1	1 / 2	2 / 1	1 / 1
	01	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
	03	0 / 0	0/0	0/0	0 / 1	0 / 1	2/3	0/0	1/2	1 / 1	1 / 1
	05	0 / 0	1 / 1	0/0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 1
ms	07	0/0	0/0	0/0	0/0	0/0	0 / 0	0/0	0/0	0/0	0/0
Da	10	0/0	0/0	0/0	0/0	0/0	0 / 0	0/0	0 / 0	0/0	0/0
eq	11	0/0	0/0	0 / 1	0/0	0/0	1/1	1/1	0/0	0/0	0/0
nat	14	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
m Vaccinated Dams	16	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
\sigma_a	17	0/0	0/1	0/0	0/1	0/1	0/1	1/1	0/1	0/0	0/0
E	20	0/0	0/0	0/0	0/1	0/0	0/0	0/0	0/0	0/0	0/0
fro	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
E	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/1
tr	26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Calves Fed Colostrum fro	28 29	0/0	0/0	0/0	0/0	0/0	0/0	1/1 0/0	0/1	1 / 1 0 / 1	0 / 1 1 / 2
ű	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/1	0/0
ed	34	0/0	1/2	0/0	0/0	0/0	0/0	0/0	1/2	0/0	1/1
S F	36	0/0	0/0	0/0	0/1	0/0	0/0	0/1	0/0	0/1	0/0
llve	38	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Ca	40	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
	40	U / U	0/0	0 / 0	U/U	U/U	U / I	U / I	0/0	U/U	0/0

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<sup>\*</sup>Day 0 = day of challenge # Animals were scored in the AM and PM (Score recorded as AM / PM) -= Animal no longer on study Fecal Scores: 0 = Normal; 1, 2, 3 = Abnormal

### Mortality (Yes / No)

nent up	ıl ID	Mortali	ty (Yes/No)
Treatment Group	Animal ID	Yes	No
	02		X
S	04	X X	
am	04 08 09	X	
1 D	09		X
tro	12 13 15		X X X X
001	13		X
ıC	15		X
.on	18		X
ո քո	19	X	
Calves fed colostrum from Control Dams	22		X
str	25	X	
solc	27		X X X X
d c	30		X
s fe	32		X
ve	33		X
$\mathbb{C}^{\mathbf{a}}$	35	X	
	37		X
	39		X
	01		X
S	03		X
am	05		X
Ď	07		X
ted	10 11		X
na	11		X
cci	14		X
Va	16		X
from Vaccinated Dams	17		X
fre	20 21		X
	21		X
trı	24		X
solo	26		X
ر د	28		X
Calves Fed Colostrum	29		X X X X X X X X X X X X X X X X X X X
S F	31		X
lve	34		X
Ca	36		X
	38		X
	40		X

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Study Type	Efficacy
Pertaining to	Bovine Rotavirus serotype G6 (BRV G6)
<b>Study Purpose</b>	Demonstrate passive immunity against diarrhea caused by BRV G6 in calves
<b>Product Administration</b>	2 doses of vaccine administered intra muscularly (IM) approximately 6 and 3 weeks to pregnant heifers prior to calving.
Study Animals	Thirty-nine (39) neonatal calves were removed from their dams prior to first nursing; 19 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with the vaccine; 20 calves were fed colostrum/milk from pre-assigned heifers (one calf to one heifer) that had been vaccinated previously with a placebo. Calves were negative for pre-colostral virus neutralizing (VN) BRV antibody titer.
<b>Challenge Description</b>	BRV, virulent Lincoln strain, administered orally at 8 to 12 hours of age
Interval observed after	Calves were observed up to 9 days post-challenge for clinical
challenge	signs.
Results	Calves were observed for fecal consistency, appetite, attitude, and dehydration,.  See the following tables for individual raw data.
<b>USDA Approval Date</b>	10/25/2004

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### **Fecal Consistency Scoring:**

t		Days of observation post-challenge*											
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #		
	02	0 / 0	0 / 0	2/2	2/2	2/3	2/2	3/3	2/2	3/3	2/-		
	03	0 / 0	1 / 1	3/3	2/2	3/3	-	-	-	-	-		
us	05	0 / 0	0 / 0	3/3	1 / 1	1 / 1	2/2	2/2	2/2	3/3	3/3		
Calves Fed Colostrum from Control Dams	07	0 / 0	1 / 1	0 / 0	0/0	0 / 0	0 / 0	0 / 0	3/3	2/2	2/2		
	10	0 / 0	0 / 0	3/3	1 / 1	3/3	3/3	3/3	2/2	3/3	-		
tro	12	1 / 1	2/2	3/3	3/3	3/3	2/2	-	-	-	-		
0 n1	14	0 / 0	2/2	2/2	1 / 1	2/2	2/2	3/3	3 / 3	-	-		
Ŭ	15	0 / 0	2/2	2/2	3/3	-	-	-	-	-	-		
m m	17	0 / 0	0 / 0	3/3	3/3	2/2	2/2	1 / 1	3/3	2/2	2/2		
frc	20	0 / 0	2/3	1 / 1	2/2	1 / 1	1 / 1	0/0	0/0	3/3	3/3		
В	22	0 / 0	3/3	3/3	3/3	3/3	2/2	0/0	2/2	0/0	0/0		
ru	23	0/0	2/2	2/2	1/1	0/0	0/0	3/3	2/2	1/1	1/1		
ost	26	0/0	3/3	3/3	2/2	0 / 0	3 / 3	0 / 0	0 / 0	2/2	1 / 1		
Joj	28	0/0	3/3	3/3	-	-	-	-	-	-	-		
] C	30	0/0	3/3	2/2	1/1	2/2	0/0	0/0	2/2	2/2	2/2		
Jec	32	0/0	2/2	2/2	3/3	2/2	0/0	0/0	0/0	2/2	2/2		
S	34	0/0	0/0	3/3	2/2	2/2	1/1	2/2	2/2	2/2	2/2		
lve	35	0/0	0/0	3/3	2/2	3/3	3/3	3/3	3/3	3/3	-		
$C_{\mathbf{a}}$	38	0/0	3/3	2/2	1/1	1/1	3/3	3/3	3/3	2/2	2/2		
	39	0/0	2/2	3/3	3/3	3/3	2/2	3/3	3/3	-	-		
	01	0/0	0/0	0/0	0/0	0/0	1/1	0/0	1/1	0/0	3/3		
	04	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1	3/3	3/3		
eq	06	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/2	1/1	1 / 1		
ıat	09	0/0	2/2	1/1	0/0	3/3	3/3	3/3	3/3	2/-	- 1 / 1		
cir	11	0/0	0/0	0/0	1/1	0/0	0/0	3/3	1/1	1/1	1/1		
ac	13	0/0	1/1	0/0	1/1	2/2	3/3	2/2	2/2	3/3	2/2		
from Vaccinated	16 18	0/0	2 / 2 0 / 0	0/0	2 / 2 0 / 0	3 / 3	3 / 3	2 / -	2/2	3/3	3/3		
ou	19	0/0	0/0	1/1 2/2	2/2	0/0	1/1	0/0	3/3	3/3	3/3		
		_ , _		0/0	2/2	1/1	2/2	2/2	3/3	1/1	0/0		
	21 24	0/0	1/1 2/2	2/2	1/1	0/0	1/1	0/0	0/0	0/0	0/0		
tr	25	0/0	2/2	0/0	0/0	2/2	0/0	1/1	1/1	2/2	3/3		
Calves Fed Colostrum Dams	27	0/0	0/0	1/1	0/0	0/0	0/0	2/2	1/1	3/3	1/1		
$C_0$	29	0/0	0/0	0/0	1/1	0/0	1/1	2/2	2/2	2/2	0/0		
þ	31	0/0	0/0	1/1	0/0	3/3	2/2	3/3	3/3	1/1	1/1		
Fe	33	0/0	0/0	3/3	1/1	0/0	3/3	3/-	-	-	-		
es Is	36	0/0	0/0	1/1	1/1	2/2	3/3	2/2	2/2	2/2	1 / 1		
Calves Dams	37	0/0	0/0	1/1	0/0	3/3	3/3	3/3	2/2	-	-		
ÜÖ	40	0/0	2/2	2/2	2/2	1/1	0/0	1/1	2/2	2/2	1 / 1		

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Fecal Scores: 0, 1 = Normal; 2, 3 = Abnormal

### **Appetite Scoring:**

				Da	ys of ob	servatio	on post-	challeng	ge*		
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #,0	8 AM/PM #	9 AM/PM #
	02	0 / 1	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	2/-
	03	0 / 0	0 / 0	0 / 0	0 / 0	0 / 1	-	-	-	-	-
JS	05	0 / 1	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0
lan (	07	0 / 0	0 / 1	1 / 2	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
	10	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 2	-
Calves Fed Colostrum from Control Dams	12	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0 / 1	-	-	-	-
<b>[</b> ,	14	0 / 0	1/2	0 / 0	0 / 1	0 / 1	0 / 0	0 / 1	0 / 2	-	-
l a	15	0 / 0	1/0	0 / 1	1 / 1	-	-	-	-	-	-
ror	17	0 / 0	0 / 1	0 / 1	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 1	0 / 0
n f	20	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0
	22	0 / 0	0 / 0	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
ost	23	0 / 0	1 / 1	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
[9]	26	0 / 0	0 / 1	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 1	1/0	0 / 0
) p	28	0 / 0	0/0	0/0	1 / -	-	-	-	-	-	-
Fe	30	0 / 0	0/0	0/0	0 / 1	0/0	0 / 0	0/0	0 / 0	0/0	0/0
ves	32	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Ę	34	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
	35	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/2	-
	38	0/0	2/1	0/0	0/0	0/0	0/0	0/0	0/0	0 / 0	0/0
	39	0/0	0/0	0 / 1	0/0	0/0	0/0	0 / 1	2/2	-	-
	01	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
us	04	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
)ar	06	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
from Vaccinated Dams	09	0/0	1/0	0/0	0/0	0 / 1	0 / 1	0/0	0 / 1	2 / -	-
ate	11	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
ci l	13	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 0	0 / 0	0/0
'ac	16	0/0	0/0	0/0	0/0	0/0	0/0	2/-	-	-	-
l d	18	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
ror	19	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/1	0/0
_	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
ost	25	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
[O]	27 29	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
l g		0/0	0/0	0/0	0/0	0/0	0/0	0/0			0/0
Fe	31 33	0 / 1	1/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
ves		0/0		0/1		0/0		0/0	0/0	0/0	0/0
Calves Fed Colostrum	36		0/0		0/0		0/0		0/0		
1	37	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	-	-
	40	0 / 0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Appetite Scores: 0 = Normal; 1, 2 = Abnormal

### **Attitude Scoring:**

					Da	ys of ob	servatio	on post-	challeng	ge*		
STATE   1/2   1/	Treatment Group	Animal ID	-	AM/PM	AM/PM		AM/PM		AM/PM		_	9 AM/PM #
Note		02	0 / 1	0 / 1	1 / 1	1/2	1/2	2/2	2/2	2/2	2/2	3 / -
The late   1				1 / 2			2/2			-		
SS   O/O	Su		0 / 0	0 / 1	2/2	1/2		2/2	1/2		2/2	2/2
SS   O/O	)an											1 / 1
SS   O/O									2/2	1 / 1	2/2	-
SS   O/O	ıtr								-	-	-	-
SS   O/O	Or						1/2	2/2	2/2	2/2	-	-
SS   O/O	m (									-		
SS   O/O	roi											
SS   O/O	m f											
SS   O/O	ıru.											<b>+</b>
SS   O/O	lost											1
SS   O/O	C0]						1/0	2/2	0/0	0/0	0 / 1	1/1
SS   O/O	p <sub>o</sub>						-			-		
SS   O/O	F.						_					
SS   O/O	ves											
SS   O/O	Cal.											
The first of the												1
The large of the											1	1/2
The late of the												-
The late   The late												
The state of the	ms											1
The state of the	Da											
The state of the	eq											
The state of the	nat									_		_
The state of the	ccii									1/2		
The state of the	Vac									1 / 2		
The state of the	Ē											
24  0/0  1/2  1/2  0/1  0/0  0/0  0/0  0/0	fro											
1	ш											
27 0/0 1/0 0/1 0/0 0/0 0/0 1/2 0/1 1/2 1/1  29 0/0 0/0 0/0 0/0 0/0 0/1 1/1 0/1 1/2 1/1  29 0/0 0/0 0/0 0/0 0/0 0/1 1/1 0/1 1/1 1/0  31 0/1 1/1 0/0 0/0 1/2 1/1 1/2 2/2 1/0 0/0  33 0/0 0/0 0/0 0/2 0/0 1/1 2/2 3/  36 0/0 0/0 0/0 0/1 0/1 1/2 0/1 1/1 0/1 0/1  37 0/0 0/0 0/0 0/0 1/2 1/2 1/2 2/2 1/2	tru											1
29 0/0 0/0 0/0 0/0 0/0 0/0 0/1 1/1 0/1 1/1 1	los											
31	$C_0$											
33 0/0 0/0 0/0 1/1 2/2 3/ 36 0/0 0/0 0/0 0/0 0/1 0/1 1/2 0/1 1/1 0/1 0/1 37 0/0 0/0 0/0 0/0 1/2 1/2 1/2 2/2 1/2	eq											
36 0/0 0/0 0/0 0/1 0/1 1/2 0/1 1/1 0/1 0/1 37 0/0 0/0 0/0 0/0 1/2 1/2 2/2 1/2	SF											
37 0/0 0/0 0/0 1/2 1/2 2/2 1/2	lve											
	Ca											
<b>40</b> 0/0 0/1 0/1 0/1 0/1 0/0 0/0 0/1 0/1 0/0												

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Attitude Scores: 0 = Normal; 1, 2, 3 = Abnormal

### **Dehydration Scoring:**

				Da	ys of ob	servatio	on post-	challeng	ge*		
Treatment Group	Animal ID	0 AM/PM #	1 AM/PM #	2 AM/PM #	3 AM/PM #	4 AM/PM #	5 AM/PM #	6 AM/PM #	7 AM/PM #	8 AM/PM #	9 AM/PM #
	02	0 / 0	0 / 0	1 / 1	1/2	1/2	2/2	2/2	2/2	2/2	3 / -
	03	0 / 0	1 / 1	1 / 2	2/2	2/3	-	-	-	-	-
S	05	0 / 0	0 / 0	2/2	1/2	1 / 1	1/2	1/2	1/2	2/2	2/2
am	07	0 / 0	0 / 1	1 / 1	0 / 1	0/0	0 / 0	0 / 0	2/2	1/2	1 / 1
Calves Fed Colostrum from Control Dams	10	0/0	0/0	1 / 2	1 / 1	0/2	2/2	2/2	1 / 1	2/2	-
tro	12	0 / 1	0 / 1	0 / 2	2/2	2/2	2/3	-	-	-	-
on	14	0/0	1 / 1	1 / 2	1/2	1/2	2/2	2/2	2/2	-	-
n C	15	0 / 0	1 / 2	2/2	2/2	-	-	-	-	-	-
ron	17	0 / 0	0 / 1	2/2	2/2	2/2	2/2	1 / 1	2/2	2 /2	2/2
n fi	20	0 / 0	1 / 2	0 / 0	1/2	0 / 0	1 / 1	1/0	0 / 0	1 / 2	1 / 2
rur .	22	0 / 0	2/2	1 / 2	1/2	1/2	0 / 1	0 / 0	0 / 1	0 / 0	0 / 0
ostı	23	0 / 0	1 / 2	1 / 1	1 / 1	1 / 1	1/ 1	1/2	1 / 1	0 / 1	1 / 1
Jol	26	0 / 0	2/2	2/2	2/2	1/0	2/2	0 / 0	0 / 0	0 / 1	1 / 1
d (	28	0 / 0	1 / 2	3/3	-	-	-	-	-	-	-
Fe	30	0 / 0	2/2	1 / 1	2/2	0 / 1	0 / 0	1 / 2	2/2	2/2	1 / 2
/es	32	0 / 0	1 / 2	1 / 2	2/2	2/2	0 / 1	1 / 1	0 / 0	2/2	1 / 2
alv	34	0 / 0	0 / 0	1 / 2	2/2	1 / 2	1 / 1	1 / 1	1 / 2	1 / 2	0 / 1
	35	0 / 0	0 / 0	1 / 1	1 / 1	1/2	1 / 2	1 / 2	2/2	2/2	-
	38	0 / 0	1/2	2/2	1 / 1	0/0	1/2	1/2	1/2	1 / 1	1/2
	39	0 / 0	1 / 1	1 / 2	2/2	2/2	2/2	2/2	2/2	-	-
	01	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
ns	04	0 / 0	0 / 0	0 / 0	0/0	0/0	0/0	0/0	0/0	0 / 1	1 / 2
Эаг	06	0 / 0	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	1 / 2	0 / 1	0/0
from Vaccinated Dams	09	0/0	1/1	0 / 1	0/0	2/2	1/2	2/2	1/2	3 / -	-
ate	11	0/0	0/0	0 / 1	0/0	0/0	0/0	1/2	0 / 1	0/0	0/0
cin	13	0/0	0/0	0/0	0/0	1/2	2/2	0 / 1	1 / 2	2/2	1 / 2
/ac	16	0/0	0 / 1	0/0	1/2	2/2	2/2	3 / -	-	-	-
n /	18	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	1/2	1/2	1/2
roi	19	0/0	0/1	2/2	1/2	0/0	0/0	0/0	1/2	1/2	2/2
_	21	0/0	0/0	0/0	1/2	0/1	1/2	2/2	1/2	1/1	1/1
ru	24	0/0	1/2	1/2	0/1	0/0	0/0	0/0	0/0	0/0	0/0
ost	25	0/0	1/2	0/0	0/0	0/1	0/0	0/0	1/1	0/1	1/2
Col	27	0/0	1/0	0/1	0/0	0/0	0/0	1/2	0/1	1/2	1/1
Calves Fed Colostrum	29	0/0	0/0	0/0	0/0	0/0	0 / 1	1/1	0/1	1/1	1/0
F.	31	0/1	1 / 1 0 / 0	0/0	0/0	1/2	1/1 2/2	1/2 2/-	2/2	1/0	0/0
ves	36	0/0	0/0	0/2	0/0	1 / 1 0 / 1	1/2	0/1	1/1	0 / 1	0 / 1
Cal	37	0/0	0/0	0/0	0/1	1/2	1/2	2/2	1/1	-	-
							1				
	40	0 / 0	0 / 1	0 / 1	0 / 1	0 / 1	0/0	0/0	0 / 1	0 / 1	0/0

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<sup>\*</sup>Day 0 = day of challenge
# Animals were scored in the AM and PM (Score recorded as AM / PM)
- = Animal no longer on study
Fecal Scores: 0 = Normal; 1, 2, 3 = Abnormal

Study Type	Safety											
Pertaining to	All fraction	S										
Study Purpose	Demonstrat	e safety in c	attle unde	er field co	nditions							
Product	Two doses a						dose 6					
Administration	weeks and s	econd dose	3 weeks 1	before sch	eduled	calving						
Study Animals	Nine hundre	ed fifty-two	(952) 6-7	-month p	regnant	animals in	n 3					
, and the second	geographic	geographic locations. About 700 animals were vaccinated, the										
	remaining a	remaining animals received a placebo control.										
	Site 1: 374	(94 controls	s and 280	vaccinate	es)							
	Site 2: 355	(116 control	ls and 239	vaccinate	es)							
	Site 3: 221											
<b>Challenge Description</b>	N/A											
Interval observed	Animals we	re observed	individua	ally for 28	days at	fter first						
after vaccination	vaccination	for injection	n site reac	tions and	adverse	events.						
Results	Site 1:											
	Treatment	Depression	Injection	Diarrhea	Ataxia	Abortion	Other					
	Group		site									
	Controls	0	Swelling 0	0	0	0	0					
	Vaccinates	2*	0	0	0	0	1**					
	*Animal 331 was	reported to be de	pressed and so	ore (Study Day	1). Animal	388 was descr	_					
	sluggish, no appe **Animal 067 ex			tudy Day 1)								
	rimmar 607 ex	perioneed a cervic	ai proiapse (5	tudy Day 1).								
	Site 2:											
	Treatment	Depression	Injection	Diarrhea	Ataxia	Abortion	Other					
	Group		site									
	G 4 1	0	Swelling	0	0	1						
	Vaccinates	0	0	0	0	0	1*					
	* Dystocia and de		v	-	U	U	1					
	Site 3:											
	Treatment	Depression	Injection	Diarrhea	Ataxia	Abortion	Other					
	Group		site									
	Controls	0	Swelling 0	0	0	1	0					
	Vaccinates	0	0	0	0	0	1*					
	* Dystocia and de	ad calf delivered	(Study Day 20	))								
	Only 2 anin											
	depression/s											
	injection sit			vaccine re	lated lo	cal or syst	temic					
	reactions, w	ere reported	1.									
USDA Approval Date	12/07/2004											

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