

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4570.22
True Name	Bovine Rotavirus-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin- Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Scourguard 4KC - Agrimatco Limited Algeria Scourguard 4KC - No distributor specified Scourguard 4KC - SARL Belophram Scourguard 4KC - Zoetis Industria Produtos Veterinarios Ltda. Scourguard 4KC - Zoetis Industria de Produtos Scourguard 4KC - Zoetis Mexico Scourguard 4KC - Zoetis Russia Scourguard 4KC - Zoetis South Africa Ltd
Date of Compilation Summary	March 01, 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	Comparative Serology
Pertaining to	Clostridium perfringens Type C (C. perfringens Type C)
Study Purpose	Comparative serology for <i>C. perfringens</i> to show that combining fractions with satisfactory efficacy studies does not reduce the immune system. Demonstrate passive immunity against diarrhea caused by <i>C. perfringens</i> Type C
Product Administration	2 doses IM, approximately 6 weeks and 3 weeks in pregnant heifers before calving
Study Animals	Pregnant heifers 18 to 30 months old; 52 controls, and 3 groups of 53, 53 and 51 vaccinates
Challenge Description	Serological response
Interval observed after	Blood samples were collected on days 21 and 35 post-
challenge	vaccination.
Results	C. perfringens Type C Beta Toxoid potency was ≥ minimum antigen at release for all vaccinated groups and no interference was shown with the other fractions in the vaccine.
USDA Approval Date	10/25/2004

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Study Type	Efficacy
Pertaining to	Bovine Coronavirus (BCV)
Study Purpose	Demonstrate passive immunity against diarrhea caused by BCV
	in calves
Product Administration	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 l	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
/ a /	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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^{*}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 [#]	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
ပ္	13	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
lε	16	0 / 0	1/0	0 / 0	-	-	-	-	-	-	-
Calves Fed Colostrum from Control Dams	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	-	-	-	-
 	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
ब्रि	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 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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^{*}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
SI	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
D	07	0/0	0/0	0/0	1 / 1	0 / 0	0 / 0	0 / 1	1/2	1/2	0 / 1
rol	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
Co	13	0/0	0/0	0 / 1	0 / 1	1/2	0 / 1	1 / 1	1 / 2	1 / 1	2/2
ш	16	0 / 0	1 /1	0 / 1	-	-	-	-	-	-	-
Calves Fed Colostrum from Control Dams	17	0 / 0	1 / 1	0 / 1	2/2	2/2	2/3	-	-	-	-
n f	20	0 / 1	2/3	-	-	-	-	-	-	-	-
rur.	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	-	-	-	-
olo	25	0 / 0	0 / 1	0 / 1	0 / 0	0 / 1	1 / 2	1/2	3 / -	-	-
Č	28	0 / 1	1 / 2	1/2	1/2	0 / 1	0/0	1 / 1	1 / 1	2/3	-
ed	29	0 / 0	0 / 0	1 / 1	1 / 2	2/2	-	-	-	-	-
¥.	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 / 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
กลา	06	0 / 0	0 / 0	0/0	0/0	0 / 0	0/0	0 / 0	0/0	0 / 0	0/0
(ci)	08	0 / 0	0 / 0	0/0	0 / 0	0/0	0 / 0	0/0	0/0	0 / 0	
/ac	10	0 / 0	1 / 2	0 / 1	0 / 1	0/0	0 / 0	0/0	1 / 2	0 / 1	1 / 1
from Vaccinated	12	0 / 0	0 / 0	0/0	0 / 0	0 / 1	1 / 1	1/2	2/3	-	-
.or	14	0/0	1/2	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
str De	19	0/0	0 / 1	0/0	0/0	0 / 1	1/1	1/2	0/0	1/1	1/1
olo	21	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	0/0	1/2	0/1
Co	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
F	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
alv	35	0/0	0/1	0/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0
C	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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^{*}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	tion 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
18	04	0/0	2/2	1/2	2/2	1/2	2/2	-	-	-	-
Calves Fed Colostrum from Control Dams	05	0 / 0	0/0	0/0	0 / 0	0 / 1	1 / 1	1/2	1/2	1 / 1	0 / 1
Q	07	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 1	1/2	1/2	0 / 1
ro L	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	0/0	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
Ē	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	-	-	-	-
 원	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	-	-	-	-	-
T.	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
[R]	36	0 / 0	1 / 1	1/2	0 / 1	0 / 1	1 / 2	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
na1	06	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
Sci	08	0 / 0	0 / 0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
) a	10	0 / 0	1 / 1	0 / 1	0 / 1	0/0	0/0	0/0	1/2	0 / 1	1 / 1
from Vaccinated	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
_ 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
Tr. Da	19	0 / 0	0 / 1	0/0	0 / 0	0 / 1	1 / 1	1/2	0 / 0	1 / 1	1 / 1
So	21	0 / 0	0 / 0	0/0	0 / 0	0/0	0/0	0 / 1	0/0	1 / 1	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
þ	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
alv	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

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

Mortality (Yes / No)

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^{*}Day 0 = day of challenge # Animals were scored in the AM and PM (Score recorded as AM / PM)

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	cherichia coli K99 (E. coli K99) emonstrate passive immunity against diarrhea caused by E. coli 29 in neonatal calves doses of vaccine administered intramuscularly (IM) proximately 6 and 3 weeks to heifers prior to calving. venty-eight (28) neonatal calves were removed from their ms prior to first nursing: 20 calves were fed colostrum/milk om pre-assigned heifers (one calf to one heifer) that had been ccinated previously with the vaccine; 8 calves were fed lostrum/milk from pre-assigned heifers (one calf to one heifer) at had been vaccinated previously with a placebo (controls). alves were negative for pre-colostral E coli antibody titer (8). coli administered orally at 8 to 12 hours of age to calves alves were observed up to 6 days post-challenge for mortality ortality rate was calculated for each treatment group.									
Product Administration	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 rate was calculated for each treatment group. 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.									
USDA Approval Date	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
Product Administration	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
USDA Approval Date	07/29/2004

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Fecal Consistency Scoring:

					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	1/1	1 / 1	2/2	2/2	2/2	2/2	2/2	2/2	1 / 1
80	04	0 / 0	0 / 0	1 / 1	1/ 1	1 / 1	1 / 1	-	-	-	-
m e	08	0 / 0	1 / 1	0 / 0	1 / 1	0 / 0	0 / 0	1 / 1	1 / 1	0 / -	-
ΔÄ	09	0 / 0	0/0	2/2	2/2	2/2	2/2	2/2	2/2	0 / 1	1 / 1
Calves fed colostrum from Control Dams	12	0 / 0	0 / 0	0/0	0/0	1 / 1	1 / 1	1 / 1	1 / 1	1 / 1	1 / 1
l io	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
Ji O	18	0 / 0	0 / 0	2/2	0 / 0	0 / 0	1 / 1	1 / 1	0 / 0	1 / 1	0 / 0
l fr	19	0 / 0	0 / 0	1 / 1	2/2	1 / 1	1 / 1	1 / 1	-	-	-
l ü	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	-	-	-	-
50 50	27	0 / 0	0 / 0	1 / 1	0 / 0	0/0	0 / 0	0/0	0 / 0	0 / 0	0/0
) p	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
<u>v</u> e:	33	0 / 0	0 / 0	0/0	0 / 0	0/0	1 / 1	1 / 1	1 / 1	1 / 1	0 / 0
	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
l 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	2/2	1/1	1/1	1/1	0/0	0/0	0/0	0/0
l at	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
\sqrt{a}	17	0/0	2/2	0/0	1/1	1/1	2/2	1/1	1/1	0/0	0/0
E	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
E	24 26	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/1 0/0
<u>‡</u>	28	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	1/1	1 / 1	1 / 1 1 / 1	1 /1 2 / 2
ŭ	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
ed	34	0/0	2/2	0/0	1/1	0/0	1/1	1/1	2/2	0/0	1/1
	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	1/1	0/0	0/0	0/0	0/0	0/0
౮	40	0/0	0/0	0/0	0/0	0/0	1/1	1/1	0/0	0 / 1	0/0
	τυ	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1/1	1/1	0/0	0/1	0/0

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^{*}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:

			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 / -	-			
	09	0 / 0	0 / 0	0 / 1	0 / 0	0 / 0	0 / 1	0 / 0	0 / 0	0 / 0	0 / 0			
	12	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0			
	13	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0			
	15	0 / 0	0 / 0	0/0	0/0	0/0	0 / 0	0 / 0	0 / 0	0 / 0	0/0			
	18	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0/0			
fr fr	19	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	2/2	-	-	-			
	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	-	-	-	-			
 6	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			
fe 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			
	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			
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	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
lat	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			
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	17	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
E	20	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
fr.	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
Ξ	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
l î	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	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
ပိ	29	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
eq	31	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
E S	34	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
lve	36	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
$C_{\mathbf{a}}$	38	0/0	0/0	0/0	0/0	0/0	0/0	0/0	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			

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^{*}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	-	-	-	-			
Calves fed colostrum from Control Dams Trea	08	0 / 1	1/2	1/2	2/2	2/2	2 /2	2 /2	2 /2	2 / -	-			
	09	0 / 0	0 / 0	0 / 1	0 / 0	1/2	1 / 1	2/2	2/2	2/2	1/2			
	12	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	1 / 1	2/2	1 / 1	1/1	1 / 1			
	13	0 / 0	0 / 0	1/2	0 / 1	0/0	0 / 0	0/0	1/2	1 / 1	0 / 1			
	15	0 / 0	0/0	0/0	1 / 1	0 / 1	1/2	1/2	1 / 1	0 / 0	0 / 0			
	18	0 / 0	0 / 1	1/2	1 / 1	1 / 1	0 / 1	1 / 1	0 / 0	0 / 1	0 / 1			
l fr	19	0 / 0	0 / 0	1 / 1	1/2	1 / 1	2/2	2/2	-	-	-			
l a	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	-	-	-	-			
 6	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			
]a	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 m	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			
p;	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			
_\a	17	0/0	0 / 1	0/0	0 / 1	0/0	0 / 1	1 / 1	0 / 1	0/0	0/0			
lε	20	0/0	0/0	0/0	0 / 1	0/0	0/0	0/0	0/0	0/0	0/0			
<u> </u>	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0			
l E	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1			
	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	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			
<u>v</u> e.	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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^{*}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:

					Davs of o	bservatio	on post-c	hallenge [*]	÷		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 / 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	-	-	-	-											
m Vaccinated Dams Calves fed colostrum from Control Dams Treatment Group	08	0 / 1	1 / 2	1 / 2	2/2	2/2	2/2	2/2	2/2	3 / -	-											
	09	0 / 0	0 / 0	0 / 1	0 / 0	1/2	1 / 1	2/2	2/2	2/2	1/2											
	12	0 / 0	0 / 0	0 / 0	0 / 0	1 / 1	1 / 1	2/2	1 / 1	1 / 1	1 / 1											
	13	0 / 0	0/0	1 / 2	0 / 1	0 / 0	0 / 0	0 / 0	1/2	1 / 1	0 / 1											
	15	0 / 0	0 / 0	0/0	1 / 1	0 / 1	1/2	1/2	1 / 1	0 / 0	0 / 0											
om	18	0 / 0	0 / 1	1 / 2	1 / 1	1 / 1	0 / 1	1 / 1	0 / 0	0 / 1	0 / 1											
ı fr	19	0 / 0	0 / 0	1 / 1	1/2	1 / 1	2/2	2/3	-	-	-											
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	2/3	-	-	-	-											
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 fec	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	2/3	-	-	-											
•	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											
pa	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											
cii	16	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0											
Vac	17	0 / 0	0 / 1	0/0	0 / 1	0 / 1	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											
fro	21	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0											
m	24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1											
Lr.	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	1/1											
ve	36	0/0	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	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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^{*}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)
Study Purpose	Demonstrate passive immunity against diarrhea caused by BRV
	G6 in calves
Product Administration	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
CI II D : 4:	titer.
Challenge Description	BRV, virulent Lincoln strain, administered orally at 8 to 12
Interval observed after	hours of age Colves were absorved up to 0 days next abellance for clinical
	Calves were observed up to 9 days post-challenge for clinical
challenge Results	signs. Calves were observed for fecal consistency, appetite, attitude,
Results	and dehydration,.
	and denydration,.
	See the following tables for individual raw data.
USDA Approval Date	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				
)ar	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	-				
Calves Fed Colostrum from Control Dams	12	1 / 1	2/2	3/3	3/3	3/3	2/2	-	-	-	-				
	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				
lves	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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^{*}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	-	-	-	-	-
Calves Fed Colostrum from Control Dams Treatment Group	05	0 / 1	0/0	0/0	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0/0
	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	-
	12	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 1	-	-	-	-
	14	0 / 0	1/2	0 / 0	0 / 1	0 / 1	0 / 0	0 / 1	0 / 2	-	-
	15	0 / 0	1/0	0 / 1	1 / 1	-	-	-	-	-	-
	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
L I	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
Col	26	0 / 0	0 / 1	0/0	0/0	0/0	0/0	0/0	0 / 1	1 / 0	0 / 0
) pa	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
	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
ns	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
d I	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
cin	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/-	- 0 / 0	- 0 / 0	- 0 / 0
n /	18 19	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
roi				0/0	0/0	0/0	0/0	0/0	0/0	0/1	
m f	21 24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
[r.n]	25	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
lost	27	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
C ₀]	29	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
pe pe	31	0 / 1	1/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
F.	33	0/0	0/0	0/0	0/0	0/0	0/0	2/-	-	-	-
ves	36	0/0	0/0	0/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Calves Fed Colostrum from Vaccinated Dams	37	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0 / 1	-	-
											0 / 0
	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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^{*}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*											
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	Calves Fed Colostrum from Control Dams		0 / 0	0 / 1	2/2	1/2		2/2	1/2		2/2	2/2			
SS O/O												1 / 1			
SS O/O									2/2	1 / 1	2/2	-			
SS O/O	m Contro								-	-	-	-			
SS O/O							1/2	2/2	2/2	2/2	-	-			
SS O/O										-					
SS O/O	roi														
SS O/O	m f														
SS O/O	ıru.											 			
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 _o						-			-					
SS O/O	F.						_								
SS O/O	ves														
SS O/O	Cal.														
The first of the												-			
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														
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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^{*}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	-	-	-	-	-
Calves Fed Colostrum from Control Dams	05	0/0	0/0	2/2	1/2	1 / 1	1/2	1/2	1/2	2/2	2/2
	07	0 / 0	0 / 1	1 / 1	0 / 1	0 / 0	0 / 0	0 / 0	2/2	1/2	1 / 1
	10	0 / 0	0 / 0	1 / 2	1 / 1	0/2	2/2	2/2	1 / 1	2/2	-
	12	0 / 1	0 / 1	0 / 2	2/2	2/2	2/3	-	-	-	-
	14	0/0	1/1	1 / 2	1/2	1 / 2	2/2	2/2	2/2	-	-
	15	0/0	1/2	2/2	2/2	-	-	-	-	-	-
.ro	17	0/0	0 / 1	2/2	2/2	2/2	2/2	1/1	2/2	2 /2	2/2
m 1	20	0/0	1/2	0/0	1/2	0/0	1/1	1/0	0/0	1/2	1/2
tru	22	0/0	2/2	1/2	1/2	1/2	0/1	0/0	0 / 1	0/0	0/0
losı	23	0/0	1/2	1/1	1/1	1/1	1/1	1/2	1/1	0/1	1/1
Co	26	0/0	2/2	2/2	2/2	1/0	2/2	0/0	0 / 0	0 / 1	1 / 1
eq	28 30	0/0	1/2 2/2	3 / 3	2/2	0 / 1	0/0	1 / 2	2/2	2/2	1/2
SF	32	0/0	1/2	1/1	2/2	2/2	0/0	1/2	0/0	2/2	1/2
lve	34	0/0	0/0	1/2	2/2	1/2	1/1	1/1	1/2	1/2	0/1
Ca	35	0/0	0/0	1/1	1/1	1/2	1/1	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
S	04	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/2
am	06	0/0	0/0	0/0	0/0	0/0	0/0	0/0	1/2	0 / 1	0/0
l D	09	0/0	1/1	0 / 1	0/0	2/2	1/2	2/2	1/2	3 / -	-
ted	11	0/0	0/0	0 / 1	0/0	0/0	0/0	1/2	0 / 1	0/0	0/0
ina	13	0/0	0/0	0/0	0/0	1/2	2/2	0 / 1	1/2	2/2	1/2
acc	16	0 / 0	0 / 1	0 / 0	1/2	2/2	2/2	3 / -	-	-	-
X	18	0 / 0	0 / 0	0/0	0/0	0 / 0	0 / 0	0 / 1	1/2	1/2	1/2
omo	19	0 / 0	0 / 1	2/2	1/2	0/0	0 / 0	0 / 0	1/2	1/2	2/2
ı fr	21	0/0	0/0	0/0	1/2	0 / 1	1/2	2/2	1/2	1 / 1	1 / 1
l un.	24	0 / 0	1/2	1/2	0 / 1	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
ostr	25	0 / 0	1/2	0 / 0	0/0	0 / 1	0 / 0	0 / 0	1 / 1	0 / 1	1/2
Calves Fed Colostrum from Vaccinated Dams	27	0/0	1/0	0 / 1	0/0	0/0	0 / 0	1 / 2	0 / 1	1/2	1 / 1
d C	29	0/0	0/0	0/0	0/0	0/0	0 / 1	1/1	0 / 1	1/1	1/0
Fe	31	0 / 1	1/1	0/0	0/0	1/2	1/1	1/2	2/2	1/0	0 / 0
ves	33	0/0	0/0	0/2	0/0	1/1	2/2	2 / -	-	-	-
alv	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	-	-
	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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^{*}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	Safety All fractions												
Study Purpose	Demonstrate safety in cattle under field conditions												
Product	Two doses administered intramuscularly (IM) with the first dose 6												
Administration	Two doses administered intramuscularly (IM) with the first dose 6 weeks and second dose 3 weeks before scheduled calving												
Study Animals		Nine hundred fifty-two (952) 6-7-month pregnant animals in 3											
		geographic locations. About 700 animals were vaccinated, the											
	0 0 1	emaining animals received a placebo control.											
		Site 1: 374 (94 controls and 280 vaccinates) Site 2: 355 (116 controls and 239 vaccinates)											
		ite 2: 355 (116 controls and 239 vaccinates)											
	Site 3: 221	()								
Challenge Description	N/A												
Interval observed		animals were observed individually for 28 days after first											
after vaccination		accination for injection site reactions and adverse events.											
Results	Site 1:												
	Treatment	Treatment Depression Injection Diarrhea Ataxia Abortion Other											
	Group	Treatment Depression Injection Diarrhea Ataxia Abortion Other Group Site Swelling											
	Swelling												
	Vaccinates	Controls 0 0 0 0 0											
	*Animal 331 was	_	Ŭ	U	U	v							
	sluggish, no appe	tite (Study Day 3)).	, ,	-)								
	**Animal 067 ex	perienced a cervic	cal prolapse (S	tudy Day 1).									
	Site 2:												
	Treatment	Depression	Injection	Diarrhea	Ataxia	Abortion	Other						
	Group		site										
	_		Swelling										
	Controls	0	0	0	0	1	0						
	Vaccinates * Dystocia and de	0	(Study Day 24	0	0	0	1*						
	Dystocia and de	au can uchvereu	(Study Day 24	')									
	Site 3:												
	Treatment	Depression	Injection	Diarrhea	Ataxia	Abortion	Other						
	Group		site										
	G . 1	0	Swelling	0	0	1							
	Controls Vaccinates	0	0	0	0	0	1*						
	* Dystocia and de		-	•	U	U	1 '						
			, 24, 20	,									
	Only 2 anin	nals had adv	erse even	ts due to	vaccinat	tion;							
	depression/s						other. No						
	injection sit												
	reactions, w	_				J							
	,	1											
USDA Approval Date	12/07/2004												
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