Approval Date: December 12, 2003

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-187

Lasalocid

BOVATEC 68
Type A Medicated Article

for use in the manufacture of

CRYSTALYX IONO-LYX
Free-Choice Type C Medicated Protein Feed Block

For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

Sponsored By:

Ridley Block Operations Inc.
424 North Riverfront Dr.
PO Box 8500
Mankato, MN 56002-8500

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BOVATEC 68 (Lasalocid) for Pasture Cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) Type A Medicated Article

1. GENERAL INFORMATION:

a. File Number:	NADA 141-187
b. Sponsor:	Ridley Block Operations Inc. 424 North Riverfront Dr. PO Box 8500 Mankato, MN 56002-8500 Drug Labeler Code: 068287
c. Established Name:	Lasalocid
d. Proprietary Name:	BOVATEC 68 CRYSTALYX IONO-LYX
e. Dosage Form:	Oral
f. How Supplied:	Laslocid is supplied as a Type A medicated article that is used in the manufacture of a 250 pound free-choice Type C medicated protein feed block (CRYSTALYX IONO-LYX).
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	68 g lasalocid sodium/lb in the Type A medicated article and 300 g lasalocid sodium/ton in the Type C medicated feed
i. Route of Administration:	Orally, as a free-choice Type C medicated protein feed block
j. Species/Class:	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)
k. Recommended Dosage:	Feed continuously on a free-choice basis at the rate of 60 to 200 milligrams lasalocid per head per day
l. Pharmacological Category:	Ionophore

m. Indications: For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

2. EFFECTIVENESS:

a. Dosage Characterization:

Studies in pasture cattle conducted to determine the appropriate dose of lasalocid (60 – 200 mg/head/day) are summarized in the Freedom of Information Summary for BOVATEC 68 Type A medicated article for pasture cattle fed on a free-choice basis, NADA 096-298, dated December 2, 1985, and approved February 12, 1986 (51 FR 5162).

b. Substantial Evidence:

Five pivotal pasture studies were conducted to evaluate lasalocid consumption when administered in a free-choice low moisture block to stocker cattle and replacement heifers. At each study location, cattle were allotted to three pasture replicates (8 to 12 animals/group) on the basis of initial body weight. Cattle were given *ad libitum* access to a lasalocid-medicated block (300 g/ton, as-fed basis) throughout the 98-day treatment period. White salt was also provided in a separate feeder to each pasture replicate throughout the study. Cattle were rotated every 7 to 14 days to minimize potential pasture differences. The dose of lasalocid tested was determined by the consumption of medicated block. There were no adverse reactions observed in the studies. All studies used typical pasture management practices, animals, and facilities.

A. Sidney, NE (TSAH-99-9)
Investigator: Ivan Rush, Ph.D.
High Plains Agricultural Laboratory
Sidney, NE

The trial used growing beef steers (Angus and Angus crossbred) that were approximately 14 months of age. The body weights of the cattle prior to the facilities acclimation period ranged from 519 to 607 pounds. Initial body weight was used to randomize animals to three replicates, each consisting of 10 animals. Cattle were assigned to native pasture replicates of similar forage quantity and quality. The predominant forage species were crested wheat grass and lesser amounts of Buffalograss, needleandthread grass, and side oats grama. There was no supplemental feed fed during the study.

B. York, SC (TSAH-99-15)
Investigator: Don McIntyre, Ph.D.
Triple C Farms
York, SC

The trial was conducted using growing heifers bred from Brangus, Angus, and Simmental sires and crossbred dams that were predominantly of Angus, Hereford, and Gelbvieh breeds. The heifers were approximately 10 to 12 months of age. The body weights of the cattle, prior to the 2-week acclimation period, ranged from approximately 462 to 544 pounds. Initial body weight was used to randomize animals to three replicates, each consisting of 12 animals. Cattle were assigned to non-irrigated pasture replicates planted with a mixture of rye and ryegrass.

C. Wellington, CO (TSAH-99-18)
Investigator: Dallas Horton, D.V.M.
Horton Feedlot and Research Center
Wellington, CO

The trial used growing beef heifers (mixed breeding) that were approximately 9 to 12 months of age. The body weights of the cattle prior to the facilities acclimation period ranged from 586 to 613 pounds. Initial body weight was used to randomize animals to three replicates, each consisting of 8 animals. Cattle were assigned to native pasture replicates of similar forage quantity and quality. The predominant forage species were cool season grasses. There was no supplemental feed fed during the study.

D. Winterset, IA (TSAH-99-20)
Investigator: Brett Terhaar, D.V.M.
Frontier Veterinary Research and Consulting
Winterset, IA

The trial used growing beef heifers (Angus and Angus crossbred) that were approximately 14 months of age. The body weights of the cattle prior to the facilities acclimation period ranged from 485 to 650 pounds. Initial body weight was used to randomize animals to three replicates, each consisting of 8 animals. Cattle were assigned to native pasture replicates of similar forage quantity and quality. The predominant forage species were bromegrass, bluegrass, and reed canary grass. There was no supplemental feed fed during the study.

E. Wrightstown, NJ (CD-99-5)
Investigator: Ross Miller, D.V.M.
Alpharma, Inc.
Animal Science Research Station
Wrightstown, NJ

The trial used growing beef steers (Angus and Angus crossbred) that were approximately 9 months of age. The body weights of the cattle prior to the facilities acclimation period ranged from 574 to 609 pounds. Initial body weight was used to randomize animals to three replicates, each consisting of 10 animals. Cattle were assigned to native pasture replicates of similar forage quantity and quality. The predominant forage species were orchardgrass, timothy, brome, and ryegrass. Supplemental hay was fed to the cattle for a 3-week period during the study due to a prolonged drought.

Lasalocid consumption for the five studies was analyzed using a five-study pooled model. A pasture replicate was designated as an experimental unit and a period was defined as a 14-day interval during the study. There were seven 14-day intervals per study.

Results from the statistical analysis are shown in the following table:

Table 1

	Least Squares Means						
Parameter	NE-TSAH-99-9	SC-TSAH-99-15	CO-TSAH-99-18	IA-TSAH-99-20	NJ CD-98-5	Pooled Average	C.V.
Block Consumption (lb/head/day)	0.56	0.49	0.72	0.73	0.87	0.67	N/A
Lasalocid Consumption (mg/head/day)	84	163	108	112	130	119	30.95

Mean block consumption across the five studies ranged from 0.49 to 0.87 lbs/head/day. The average lasalocid consumption was 119 mg/head/day. The variability of lasalocid consumption, as calculated by the coefficient of variation (C.V.) across studies sites during the 14-day consumption periods was 30.95 %.

3. TARGET ANIMAL SAFETY:

Studies in pasture cattle conducted to determine the target animal safety of lasalocid are summarized in the Freedom of Information Summary for BOVATEC 68 Type A Medicated Article for pasture cattle fed on a free-choice basis, NADA 096-298, dated December 2, 1985, and approved February 12, 1986 (51 FR 5162).

4. HUMAN SAFETY:

Human Safety data were in the Freedom of Information Summary for NADA 96-298 dated December 2, 1985, and approved February 12, 1986 (51 FR 5162), for lasalocid for pasture cattle fed on a free-choice basis.

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that BOVATEC 68 (used in the manufacture of CRYSTALYX IONO-LYX Free-Choice Type C Medicated Protein Feed Block) when administered at 60 – 200 milligrams lasalocid per head per day in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) is safe and effective for increased rate of weight gain

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the lay person have been provided. Label directions provide detailed instruction in plain language. The drug product is not a controlled substance. Thus, the drug product is assigned OTC status, and the labeling is adequate for the intended use.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The application contains investigations conducted or sponsored by the applicant that demonstrate animal safety and substantial evidence of effectiveness.

No patents were submitted with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

CRYSTALYX IONO-LYX Free-Choice Type C Medicated Protein Feed Block