Approval Date: August 20, 2002

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-171

BOVATEC® 68 (lasalocid) Type A Medicated Article

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

Sponsored By:

Purina Mills, Inc.
P.O. Box 66812
St. Louis, MO 63166-6812

FREEDOM OF INFORMATION SUMMARY

BOVAT4EC® 68 in a Free-choice High Magnesium Mineral Block
For Pasture Cattle

1. GENERAL INFORMATION

a. File Number:	NADA 141-171
b. Sponsor:	Purina Mills, Inc. P.O. Box 66812 St. Louis, Missouri 63166-6812 Drug Labeler Code: 017800
c. Established Name:	Lasalocid
d. Proprietary Name:	Bovatec® 68
e. Dosage Form:	Type C Medicated Free-choice Mineral Block
f. How Supplied:	Lasalocid is supplied as a Type A article that is used in the manufacture of 33 1/3 and 40 pound Type C medicated mineral blocks.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	1440 g/ton in the Type C Free-choice Mineral Block.
i. Route of Administration:	Oral
j. Species/Class:	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).
k. Recommended Dosage:	60-200 mg lasalocid/head/day

l. Pharmacological Category: Lasalocid sodium (Bovatec® 68) - Ionophore

m. Indications: For increased rate of weight gain in pasture cattle.

2. EFFECTIVENESS

Five pivotal pasture studies were conducted to determine the rate and variability of lasalocid consumption when administered in a free-choice high magnesium 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 non-medicated block during a 14-day pre-study acclimation period and a lasalocid-medicated block (1440 g/ton, as-fed basis) throughout the 98-day treatment period. Cattle were rotated every 14 days to minimize differences due to pasture conditions. The dose of lasalocid tested in the study was determined by the consumption of medicated block. There were no adverse reactions observed in the studies.

A. Chester, SC

TSAH-97-44
Investigator:
Don McIntyre, Ph.D.
Carolina Quality Research
2182 Pinckney Road
Chester, SC 29706

The trial was conducted using growing beef replacement heifers of predominately Angus and Hereford breeding. The animals were approximately 7 months of age. The body weights of the cattle prior to the acclimation period ranged from approximately 395 to 450 pounds. Initial body weight was used to randomize animals to three replicates of 8 head each. Cattle were assigned to pastures of tall fescue overseeded with rye. Supplemental hay was provided to all replicates during weeks 1 through 7 of the study due to an insufficient supply of pasture forage.

B. Rosepine, LA

TSAH-97-46
Investigator:
David Sanson, Ph.D.
Rosepine Research Center
176 Research Station Road
Rosepine, LA 70659

The trial was conducted using growing beef replacement heifers of mixed breeding. The animals were approximately 10 to 12 months of age. The body weights of the cattle prior to the acclimation period ranged from approximately 548 to 648 pounds. Initial body weight was used to randomize animals to three replicates of 12 head each. Cattle were assigned to pastures of ryegrass and rye. Supplemental hay was provided to all replicates during the last 3 weeks of the study due to an insufficient supply of pasture forage.

C. Tifton, GA

TSAH-97-47
Investigator:
Gary Hill, Ph.D.
University of Georgia
Coastal Plains Experiment Station
P.O. Box 748
Moore Highway
Tifton, GA 31793

The trial was conducted using growing beef steers of mixed breeding. The animals were approximately 12 months of age. The body weights of the cattle prior to the acclimation period ranged from approximately 518 to 582 pounds. Initial body weight was used to randomize animals to three replicates of 8 head each. Cattle were assigned to pastures of improved ryegrass. There was no supplemental feed fed during the study.

D. Clayton, NM

TSAH-97-50
Investigator:
Glenn Duff, Ph.D.
New Mexico State University
Clayton Livestock Research Center
Rt. 1 Box 109
Highway 56/64 East
Clayton, NM 88415

The trial was conducted using growing beef steers of mixed breeding. The animals were approximately 8 months of age. The body weights of the cattle prior to the acclimation period ranged from approximately 318 to 470 pounds. Initial body weight was used to randomize animals to three replicates of 8 head each. Cattle were assigned to pastures of winter wheat. Sorghum sudangrass hay was provided for approximately 7 weeks during the study to prevent bloat.

E. Simpson, IL
TSAH-97-51
Investigator:
Frank Ireland, M.S.
University of Illinois
Dixon Springs Agricultural Center
Rt. 1, Box 256
Simpson, IL 62985

The trial was conducted using growing beef replacement heifers of Simmental breeding. The animals were approximately 13 to 15 months of age. The body weights of the cattle prior to the acclimation period ranged from approximately 401 to 491 pounds. Initial body weight was used to randomize animals to three replicates of 10 head each. Cattle were assigned to pastures of improved Kentucky-31 tall fescue. There was no supplemental feed fed during the study.

Lasalocid consumption from the five studies was analyzed using a five-study pooled model. A pasture replicate of animals was designated as the 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:

	Least Squares Means						
Parameter	SC TSAH-97-44	LA TSAH-97-46	GA TSAH-97-47	NM TSAH-97-50	IL TSAH-97-51	Pooled Average	C.V.
Block Consumption (lb/head/day)	0.11	0.15	0.22	0.18	0.26	0.184	N/A
Lasalocid Consumption (mg/head/day)	79.0	114.8	150.1	127.2	188.6	131.9	30.29

Mean block consumption across the five studies ranged from 0.11 to 0.26 lbs/head/day. The average lasalocid consumption was 132 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 30.29 %.

3. ANIMAL SAFETY

Target Animal Safety data were represented in NADA 096-298 Information Summary dated December 2, 1985, for Lasalocid for Pasture Cattle Fed on a Free-Choice Basis.

4. HUMAN FOOD SAFETY:

Human Food Safety data were represented in NADA 96-298 Freedom of Information Summaries dated December 2, 1985, and July 25, 2001, for Lasalocid for Pasture Cattle Fed on a Free-Choice Basis.

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA comply with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrates that lasalocid when administered at 60 to 200 mg/head/day is safe and effective for the claims indicated in Section 1 of this FOI summary. A preslaughter withdrawal period of zero days is required for the use of the lasalocid in pasture cattle.

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

Under section 512(c)(2)(F)(ii) of the FFDCA, this approval for food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the use of the product (Purina Sugar Mag Block 1440 BVT Medicated Mineral Block); containing 60 to 200 mg/head/day lasalocid for which the application was approved.

Lasalocid is under the following U.S. patent numbers:

U.S. Patent Number	Date of Expiration
4,594,354	June 10, 2003

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Purina® Sugar Mag Block BVT 1440 Type C Feed