

FREEDOM OF INFORMATION SUMMARY

NADA 096-298

BOVATEC® (lasalocid) Type A Medicated Article

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

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

Sponsored By:

Alpharma Inc.
One Executive Drive
Fort Lee, NJ 07024

I.	GENERAL INFORMATION.....	1
II.	INDICATIONS FOR USE	1
III.	DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE.....	2
IV.	EFFECTIVENESS	2
V.	ANIMAL SAFETY	12
VI.	HUMAN SAFETY	12
VII.	AGENCY CONCLUSIONS.....	12
VIII.	LABELING	13

FREEDOM OF INFORMATION SUMMARY

Bovatec® for Pasture Cattle

I. GENERAL INFORMATION

NADA: 96-298

Sponsor: Alharma Inc.
One Executive Drive
Fort Lee, NJ 07024

Established Name: Lasalocid

Trade Name: BOVATEC®

Marketing Status: OTC

EFFECT OF SUPPLEMENT:

21 CFR 558.311 currently provides for the use of lasalocid (1) to improve feed efficiency and increase rate of weight gain in cattle fed in confinement for slaughter, (2) to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when fed daily in at least one pound of supplemental feed, and (3) to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when lasalocid is provided in a free-choice supplemental feed.

The Animal Drug Availability Act of 1996 (ADAA) eliminated the requirement for dose optimization of a new animal drug. A dose or dose range is approvable up to a maximal dose that has been shown not to cause human or target animal safety concerns and does not depress animal response to the drug below that of the most efficacious dose [*Federal Register* 62(214):59832]. Based upon this provision, the effect of this supplement is to provide for free-choice and hand-fed consumption of lasalocid at a rate of not less than 60 mg nor more than 300 mg per head per day to increase rate of weight gain in pasture cattle as described in the following sections.

II. INDICATIONS FOR USE

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

III. DOSAGE FORM, DOSAGE, AND ADMINISTRATION

- Bovatec medicated premix:
- Bovatec® 20 Liquid, liquid premix containing 90.7 g lasalocid sodium activity per pound.
 - Bovatec® 68, dry premix containing 68 g lasalocid sodium activity per pound.
 - Bovatec® 150, dry premix containing 150 g lasalocid sodium activity per pound.

Bovatec Dosage:	Use Level	Indications for Use
	Feed continuously in a free-choice or hand-fed supplemental feed to provide not less than 60 nor more than 300 mg/head/day. Daily lasalocid intakes in excess of 200 mg/head/day have not been shown to be more effective than 200 mg lasalocid/head/day. For hand-fed use, the drug must be contained in at least 1 pound of supplement.	For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when fed in a free-choice or hand-fed supplemental feed.

IV. EFFECTIVENESS:

For Cattle Hand-Fed:

Summary of Efficacy Data (*As previously described in FOI Summary Dated April, 1984 for Bovatec for Pasture Cattle: 49 FR December 20, 1984, p. 49449 approval.*)

Fifteen well controlled replicated studies were conducted in slaughter, stocker, and feeder cattle on pasture in 12 different states. Duration of the studies ranged from 84 to 142 days with an average of 107 days. Steers were fed in 12 studies and heifers were fed in 3 studies. At the beginning of the study, animal weights ranged from 300 to 947 pounds and averaged 568 pounds. Each study contained replicates of nonmedicated control animals for comparison purposes.

Statistical Analysis

Analysis of variance was conducted on each study, considering the 0, 50, 100, 200, and 300 mg lasalocid treatments. The estimated treatment study means were pooled in an analysis of variance which included terms for an overall mean, treatment, location, and study within location. Each treatment-study mean was weighted by the number of replications contributing to that mean. The lower end of the statistically effective treatment dose was determined by non-overlapping confidence intervals on the predicted responses at

0, 50, and 100 mg/head/day Bovatec at the 0.95 level of confidence. The upper end of the range was determined by a linear plateau model for the treatment means.

Results of Efficacy Studies

From the pooled analysis of the fifteen pasture studies, the estimated treatment means for average daily gain (ADG) are as follows:

Control	1.26 lb/day
50 mg Bovatec	1.27 lb/day
100 mg Bovatec	1.32 lb/day
200 mg Bovatec	1.40 lb/day
300 mg Bovatec	1.42 lb/day

Average daily gain results from the pooling of the fifteen studies indicate that the one-sided 95% confidence interval on the predicted response at 0 mg/head/day Bovatec did not overlap the corresponding confidence interval at 60 mg/head/day Bovatec. The linear plateau model indicated a linear trend in average daily gain response over the interval 0 to 200 mg/head/day Bovatec with no statistical improvement in average daily gain from 200 to 300 mg/head/day Bovatec. In summary, the overall analysis of these fifteen field studies indicates that when Bovatec is incorporated in the grain supplement to slaughter, stocker, or feeder cattle between 60 and 200 mg/head/day, the cattle had a significant ($P < 0.05$) improvement in gain over cattle fed the grain supplement without Bovatec.

Details and Results of the Individual Studies

Study C-50

This study was conducted at the University of Missouri Research Farm, Columbia, Missouri, by Dr. J. A. Paterson and Dr. D. K. Bowman, Department of Animal Science, College of Agriculture, University of Missouri, Columbia, Missouri.

Forty-three steers, average initial weight 484 pounds, were fed for 112 days on fescue pasture. Only those treatments will be reported which relate to this claim. Each treatment was replicated three times with five animals per replicate.

	<u>Control</u>	<u>Bovatec 200 mg/head/day</u>
ADG (lb)	1.12	0.98

Study C-51

This study was conducted at the University of Arkansas Beef Substation at Newport, Arkansas, by Dr. J. W. Spears, Department of Animal Science, College of Agriculture, University of Arkansas, Fayetteville, Arkansas.

Sixty-four steers, average initial weight 476 pounds, were fed for 113 days on fescue pasture. Only those treatments will be reported which relate to this claim. Each treatment was replicated two times with eight animals per replicate.

	<u>Control</u>	<u>Bovatec 100 mg/head/day</u>	<u>Bovatec 200 mg/head/day</u>
ADG (lb)	0.94	0.95	0.94

Study C-62

This study was conducted at the University of Missouri Research Farm, Columbia, Missouri, by Dr. J. A. Paterson, Department of Animal Science, College of Agriculture, Columbia, Missouri.

Fifty steers, average initial weight 464 pounds, were fed for 105 days on tall fescue pasture. The carrier for the drug was either soybean oil meal or dehydrated alfalfa + distillers dried grains. Each treatment was replicated two times with five animals per replicate.

		<u>Soybean Oil Meal</u>		<u>Dehydrated Alfalfa + Distillers Dried Grains</u>	
	<u>Control</u>	<u>Bovatec 0 mg/head/day</u>	<u>Bovatec 200 mg/head/day</u>	<u>Bovatec 0 mg/head/day</u>	<u>Bovatec 200 mg/head/day</u>
ADG (lb)	0	0.94	1.10	1.05	1.15

Study C-79

This study was conducted at Kansas State University Research Farms, Manhattan, Kansas, by Dr. L. Corah and Dr. J. G. Riley, Department of Animal Science, College of Agriculture, Kansas State University, Manhattan, Kansas.

Eighty-eight steers, average initial weight 557 pounds, were fed for 100 days on bromegrass pasture. Each treatment was replicated four times with two replicates containing four animals and two replicates containing seven animals in each treatment.

	<u>Control</u>	<u>Bovatec 100 mg/head/day</u>	<u>Bovatec 200 mg/head/day</u>	<u>Bovatec 300 mg/head/day</u>
ADG (lb)	2.17	2.24	2.37	2.24

Study C-80

This study was conducted at Middle Tennessee Experiment Station, Springhill, Tennessee, by Dr. J. W. Holloway and Dr. J. W. High, Department of Animal Science, University of Tennessee, Knoxville, Tennessee.

Seventy-two heifers, average initial weight 625 pounds, were fed for 84 days on fescue pasture. Each treatment was replicated five times with three animals per replicate. Only those treatments will be reported which were included in the pooled analysis.

	<u>Control</u>	<u>Lasalocid 50 mg/head/day</u>	<u>Lasalocid 100 mg/head/day</u>
ADG (lb)	1.37	1.37	1.45

Study C-84

This study was conducted at the University of Arkansas Beef Substation, Newport, Arkansas, by Dr. J. W. Spears, Department of Animal Science, College of Agriculture, University of Arkansas, Fayetteville, Arkansas.

Eighty-four steers, average initial weight 758 pounds, were fed for 90 day on a) tall fescue – white clover – bermudagrass, b) rye-ryegrass – arrowleaf clover – bermudagrass, and c) wheat – ryegrass – arrowleaf clover – bermudagrass pastures. Each treatment was replicated three times with seven animals per replicate.* All animals received a total of six pounds of grain per head per day for the first 45 days of the study and 10 pounds per head per day during the remainder of the study. Cattle were slaughtered directly off the pasture study.

*One replicate of each treatment was pastured on each pasture type (a, b, or c).

	<u>Control</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>	<u>Lasalocid 300 mg/head/day</u>
ADG (lb)	1.42	1.47	1.65	1.65

Study C-91

This study was conducted at North Carolina State University Animal Science Research Farm, Raleigh, North Carolina, by Dr. J. W. Spears, Department of Animal Science, College of Agriculture, North Carolina State University, Raleigh, North Carolina.

Seventy-two steers, average initial weight of 658 pounds were fed for 126 days on tall fescue, orchardgrass, and ladino clover pastures. Each treatment was replicated three times with eight animals per replicate.

	<u>Control</u>	<u>Lasalocid 200 mg/head/day</u>	<u>Lasalocid 300 mg/head/day</u>
ADG (lb)	1.11	1.32	1.26

Study C-92

This study was conducted at Dunmor, Kentucky, by Dr. N. Bradley, Lexington, Kentucky.

Sixty-four steers, average initial weight of 458 pounds, were fed for 112 days on grass-clover mixed pastures. Each treatment was replicated two times with eight animals per replicate.

	<u>Control</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>	<u>Lasalocid 300 mg/head/day</u>
ADG (lb)	1.06	1.10	1.13	1.14

Study C-94A

This study was conducted at the Moorman Manufacturing Co. Beef Research Farm, Mindon, Illinois, by Dr. Albert Peter, Moorman Manufacturing Co., Quincy, Illinois.

Eighty steer calves, average initial weight 518 pounds, were fed for 112 days on alfalfa-orchardgrass pasture. Each treatment was replicated two times with ten animals per replicate.

	<u>Control</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>	<u>Lasalocid 300 mg/head/day</u>
ADG (lb)	1.08	1.10	1.19	1.27

Study C-102

This study was conducted at the University of Florida Experiment Station Ona, Ona, Florida, by Dr. Glyn Horton, Department of Animal Science, Ona Experiment Station, Ona, Florida.

One hundred ninety-two heifers, average initial weight 528 pounds, were fed for 112 days on Ona stargrass pastures. Each treatment was replicated three times with 16 animals per replicate.

	<u>Control</u>	<u>Lasalocid 50 mg/head/day</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>
ADG (lb)	0.99	1.04	1.05	1.15

Study C-103

This study was conducted at Southeastern Kansas Experiment Station, Kansas State University, Parsons, Kansas, by Dr. Lyle Lomas, Department of Animal Science, Kansas State University, Parsons, Kansas.

Seventy-two steers, average initial weight of 642 pounds, were fed for 112 days on smooth bromegrass pastures. Each treatment was replicated three times with eight animals per replicate.

	<u>Control</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>
ADG (lb)	1.34	1.55	1.66

Study C-156

This study was conducted at the Animal Science Research Farm, South Dakota State University, Brookings, South Dakota, by Dr. Lawrence Embry, Department of Animal Science, College of Agriculture, South Dakota State University, Brookings, South Dakota.

Sixty-four steers, average initial weight 686 pounds, were fed for 142 days on a bromegrass-alfalfa pasture. Each treatment was replicated four times with four animals per replicate.

	<u>Control</u>	<u>Lasalocid 100 mg/head/day</u>	<u>Lasalocid 200 mg/head/day</u>	<u>Lasalocid 300 mg/head/day</u>
ADG (lb)	1.33	1.28	1.39	1.56

Study C-171

This study was conducted at the Horton Feedlot and Research Center, Wellington, Colorado, by Dr. Dallas Horton, Horton Feedlot and Research Center, Wellington, Colorado.

Ninety-six heifers, average initial weight 509 pounds, were fed for 98 days on brome and western wheat grass pastures. Each treatment was replicated four times with eight animals per replicate.

	<u>Control</u>	<u>Lasalocid 50 mg/head/day</u>	<u>Lasalocid 100 mg/head/day</u>
ADG (lb)	1.42	1.51	1.53

Study C-172

This study was conducted at the Simpson Experiment Station, Pendleton, South Carolina, by Dr. D. L. Cross, Department of Animal Science, College of Agriculture, Clemson University, Clemson, South Carolina.

Sixty-three steers, average initial weight 557 pounds, were fed for 98 days on bermudagrass pastures. Each treatment was replicated three times with seven animals per replicate.

	<u>Control</u>	<u>Lasalocid 50 mg/head/day</u>	<u>Lasalocid 100 mg/head/day</u>
ADG (lb)	1.16	1.15	1.23

Study C-185

This study was conducted at the Oregon State University Research Farms (Soap Creek Ranch and Berry Creek Ranch), Corvallis, Oregon, by Dr. Dale Weber, Department of Animal Science, College of Agriculture, Oregon State University, Corvallis, Oregon.

Sixty steers, average initial weight 610 pounds, were fed for 91 days on subterranean clover, tall fescue and rye grass pastures. The study was conducted in two blocks with three treatments per block. Each treatment was replicated two times with five animals per replicate.

	<u>Control</u>	<u>Lasalocid 50 mg/head/day</u>	<u>Lasalocid 100 mg/head/day</u>
ADG (lb)	1.07	1.12	1.25

For Cattle Fed Free-Choice:

Summary of Efficacy Data (*As previously described in FOI Summary Dated December 2, 1985 for Bovatec for Pasture Cattle Fed on a Free-Choice Basis: 51 FR February 12, 1986, p. 5162-3 approval.*)

A total of 566 stocker and feeder cattle were used in nine replicated well-controlled studies on pastures in eight different states. Each study contained replicates of nonmedicated control animals for comparison purposes. Duration of the studies ranged from 84 to 112 days. Steers were used in all studies. Two pens of heifers were included in one study. A total of 306 animals received lasalocid in free-choice supplements and their rate of weight gain was compared to the rate of weight gain for 260 nonmedicated control animals. At the beginning of the studies, animal weights ranged from 436 to 848 pounds and averaged 597 pounds. Thirty-six medicated animals from two additional studies were included in the determination of average lasalocid intake and in establishing the coefficient of variation for lasalocid intake.

The initial approval for free-choice lasalocid consumption for pasture cattle did not contain provision for use in dairy and beef replacement heifers. Approval of free-choice lasalocid for dairy and beef replacement heifers was covered in a FOI Summary dated March 1987. Safety data presented in that FOI Summary remain the basis for inclusion of these classes of cattle in the free-choice lasalocid approval.

Statistical Analysis

An analysis of variance (ANOVA) was made for each study, using the average daily gain (AGD) results from both the control and Bovatec-treated groups. The variances of individual studies were found to be homogeneous (Barlett's test), and ADG results from the nine studies were pooled for an overall analysis. Treatment difference was determined using a two-tailed t-test. The consumption data, reported as average intake of Bovatec in mg per head per day (mg/hd/day), from the medicated replications in all eleven studies were evaluated for each 14-day period. These data were used to establish average lasalocid intake for each study and in making an estimation of the variance in average lasalocid intake between 14-day periods within the studies. The amount of variation in lasalocid intake was then described as a percentage of average lasalocid intake by calculating a Coefficient of Variation (C.V.).

Results

From the pooled analysis of the nine pasture studies, the estimated treatment means for average daily gain (ADG) are as follows:

Control	1.540 lb/day
Bovatec Medicated Supplements	1.602 lb/day

In summary, the overall analyses of these nine field studies indicate that when Bovatec was fed to slaughter, stocker or feeder cattle on pasture in free-choice supplemental feeds, these cattle had significant ($P=0.036$) improvement in rate of gain over cattle fed the supplements without Bovatec. Further, Bovatec was effective when received by the treated cattle with variation in average daily intake, which produced a Coefficient of Variation of 35.08%.

Details and Results of the Individual Studies

Study C-94-B

This study was conducted at Moorman Beef Research Farm, Moorman Manufacturing Co., Quincy, Illinois, by Dr. A. P. Peter, Manager, Beef Cattle Research, Moorman Manufacturing Co., Quincy, Illinois.

Ninety steers, average initial weight 512 pounds, were fed for 98 days on alfalfa-orchardgrass pastures. Each treatment was replicated three times with ten animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, g/t</u> <u>(3 reps 4000) – (3 reps 6000)</u>
ADG (lb)	0.66	0.80
Bovatec (mg/hd/day)	0.0	197.1

Study C-154

This study was conducted at the Moorman Beef Research Farm, Moorman Manufacturing Co., Quincy, Illinois, Dr. A. P. Peter, Manager, Beef Cattle Research, Moorman Manufacturing Co., Quincy, Illinois.

Forty-eight steers, average initial weight 498 pounds, were fed for 84 days on alfalfa-bromegrass pastures. Each treatment was replicated two times with eight animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, g/t</u> <u>(2 reps 1440) – (2 reps 2880)</u>
ADG (lb)	1.61	1.80
Bovatec (mg/hd/day)	0.0	187.2

Study C-84-29

This study was conducted at Oregon State University, Corvallis, Oregon, by Dr. Dale Weber, Department of Animal Science, Oregon State University, Corvallis, Oregon.

Forty-two stocker cattle (14 heifers, 28 steers) average initial weight 652 pounds, were fed for 84 days on meadow foxtail, subterranean clover, tall fescue and perennial ryegrass pastures. Each treatment was replicated three times with seven animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	2.59	2.70
Bovatec (mg/hd/day)	0.0	148.4

Study C-84-30

This study was conducted at the University of Kentucky, College of Agriculture Research Farms, Lexington, Kentucky, by Dr. James A. Boling, Department of Animal Science, University of Kentucky, Lexington, Kentucky.

Sixty-four steers, average initial weight 594 pounds, were fed for 98 days on tall fescue-Kentucky bluegrass pastures. Each treatment was replicated four times with eight animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	1.19	1.17
Bovatec (mg/hd/day)	0.0	102.1

Study C-84-31

This study was conducted at the Coastal Plains Experiment Station, Tifton, Georgia, by Dr. P. R. Utley and G. M. Hill, University of Georgia, Coastal Plains Experiment Station, Tifton, Georgia.

Fifty steers, average initial weight 681 pounds, were fed for 98 days on bahiagrass pastures. Each treatment was replicated five times with five animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid , 1440 g/t</u>
ADG (lb)	1.07	1.22
Bovatec (mg/hd/day)	0.0	161.9

Study C-84-32

This study was conducted at the Simpson Agricultural Station, Clemson, South Carolina, by Dr. Dee L. Cross, Department of Animal Science, Clemson University, Clemson, South Carolina.

Sixty-four steers, average initial weight 667 pounds, were fed for 98 days on fescue and bermudagrass pastures. Each treatment was replicated four times with eight animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	0.60	0.69
Bovatec (mg/hd/day)	0.0	113.2

Study C-84-34

This study was conducted at Johnson Farms, Parma, Idaho, by Dr. E. G. Johnson, Parma, Idaho.

Eighty steers, average initial weight 622 pounds, were fed for 98 days on irrigated alta fescue pastures. Each treatment was replicated five times with eight animals per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	1.74	1.66
Bovatec (mg/hd/day)	0.0	199.4

Study C-84-35

This study was conducted at Hoffman-La Roche, Inc., Animal Science Research Experiment Farm, Wrightstown, New Jersey, by Mr. Howard Eisenbeis, Wrightstown, New Jersey.

Sixty-four steers, average initial weight 610 pounds, were fed for 112 days on ryegrass, bromegrass, orchardgrass, clover and alfalfa mix pastures. Each treatment was replicated four times with eight animals per treatment.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	2.49	2.57
Bovatec (mg/hd/day)	0.0	186.9

Study C-84-36

This study was conducted at the University of Florida, Agricultural Research and Educational Center, Ona, Florida, by Dr. David Sanson, University of Florida, Ona, Florida.

Sixty-four steers, average initial weight 619 pounds, were fed for 98 days on Ona stargrass pastures. Each treatment was replicated four times with eight steers per replicate.

	<u>Control</u>	<u>Bovatec, as Lasalocid, 1440 g/t</u>
ADG (lb)	1.55	1.51
Bovatec (mg/hd/day)	0.0	156.7

V. SAFETY FOR THE TARGET SPECIES**For Cattle Hand-Fed:**

The target animal safety for the administration of 300 mg/head/day lasalocid to slaughter, stocker, and feeder cattle on pasture is described in FOI Summary Dated April, 1984 for Bovatec for Pasture Cattle: 49 FR December 20, 1984, p. 49449 approval. Two animal safety studies were conducted in which pasture cattle were offered 200, 600, and 1000 mg of lasalocid per head daily in one pound of grain for 90 or 98 days. No toxic effects were reported in either study, and the data indicated that lasalocid was safe at five times the proposed dosage (5 X 200 mg/head/day).

For Cattle Fed Free-Choice:

The target animal safety for the administration of 300 mg/head/day lasalocid on a free-choice basis to slaughter, stocker, and feeder cattle on pasture is described in FOI Summary Dated December 2, 1985 for Bovatec for Pasture Cattle Fed on a Free-Choice Basis: 51 FR February 12, 1986, p. 5162-3 approval. Three hundred forty-two cattle from the studies used in determining average daily drug intake were exposed to lasalocid in self-fed pasture supplements with concentrations of 1440 to 6000 g/t for periods of 84 to 112 days. No adverse reactions or dangerously excessive intakes were noted. The highest average daily intake of lasalocid for any group of cattle for one 14-day period was 596 mg per head, and intake decreased in the following periods. It was concluded that the addition of lasalocid to self-fed supplements for cattle on pasture is safe for use at various concentrations.

VI. HUMAN SAFETY

An FOI Summary was prepared with a supplemental application to NADA 96-298, approved 8/6/1982, providing for the use of lasalocid in complete feeds for cattle in confinement at the rate of 100-360 mg per head daily as detailed in 21 CFR Section 558.311. The current application is for use of lasalocid premixes for hand-feeding, or to formulate various free-choice supplemental feeds, to provide lasalocid intakes of 60 to 300 mg/head/day on a nonconfined basis; therefore, the previous FOI Summary covers the toxicity, safe concentrations of residues, metabolism, total residues, and regulatory method aspects for the use of lasalocid for nonconfined cattle.

VII. 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 demonstrates that 60-300 mg lasalocid/head/day when used in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) is safe and effective for increased rate of weight gain. However, intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the layman have been provided. Historically, the industry is familiar with the handling and mixing of Type A medicated articles into Type B and C medicated feeds. Lasalocid is not a controlled substance. Thus, labeling is adequate for the intended use.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

VIII. LABELING

The following labeling is attached:

1. Bovatec ® 68 (dry Type A Medicated Article)
2. Bovatec ® 150 (dry Type A Medicated Article)
3. Bovatec ® Liquid 20 (liquid Type A Article)
4. Blue Bird Lasalocid (Cattle Hand-Fed Supplement)
5. Blue Bird M (Ruminant Free-Choice Mineral and Vitamin Supplement)
6. Blue Bird L (Ruminant Free-Choice Mineral and Vitamin Supplement - Liquid)