Approval Date: October 20, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 096-298

BOVATEC 68, BOVATEC 91 or BOVATEC Liquid 20 (Lasalocid Sodium)

Type A Medicated Article for pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)

This supplement to the NADA provides for an alternate source of lasalocid, BOVATEC 91 Type A medicated article, in the free-choice cattle feeds codified in 21 CFR 558.311(e)(2), (3), and (4). They are the free-choice formulas containing 1440, 150 or 1088 g lasalocid/ton, respectively.

Sponsored By:

Alpharma Inc.
One Executive Drive
Fort Lee, NJ

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BOVATEC 68, BOVATEC 91, and BOVATEC Liquid 20
Type A Medicated Articles for
pasture cattle (slaughter, stocker, feeder cattle,
and dairy and beef replacement heifers)

1. GENERAL INFORMATION:

a. File Number:	NADA 096-298
b. Sponsor:	Alpharma Inc. One Executive Drive Fort Lee, NJ 07024 Drug Labeler Code: 046573
c. Established Name:	Lasalocid sodium
d. Proprietary Name:	BOVATEC 68 BOVATEC 91 BOVATEC Liquid 20
e. Dosage Form:	Type A Medicated Articles to be used in the manufacture of Type C free-choice medicated feeds.
f. How Supplied:	Type A Medicated Articles. BOVATEC 68 – 50 lb bag BOVATEC 91 – 50 lb bag BOVATEC Liquid 20 – 50 lb container Type C Free-choice medicated feeds.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	BOVATEC 68 – 68 g/lb (15%) as lasalocid sodium BOVATEC 91 – 91 g/lb (20%) as lasalocid sodium BOVATEC Liquid 20 – 90.7 g/lb (20%) as lasalocid sodium
i. Route of Administration:	Oral, by feed
j. Species/Class:	Pasture cattle (slaughter, stocker, feeder cattle,

	and dairy and beef replacement heifers)
k. Recommended Dosage:	60 – 300 mg lasalocid per head/day. Feed continuously on a free-choice basis.
l. Pharmacological Category:	Ionophore
m. Indications:	For increased rate of weight gain. Daily lasalocid intakes in excess of 200 mg per head per day have not been shown to be more effective than 200 mg lasalocid per head per day.
n. Effect of Supplement:	This supplement to the NADA provides for an alternate source of lasalocid, BOVATEC 91 Type A medicated article, in the free-choice cattle feeds codified in 21 CFR 558.311(e)(2), (3), and (4). They are the free-choice formulas containing 1440, 150 or 1088 g lasalocid/ton, respectively.

2. EFFECTIVENESS:

Effectiveness for lasalocid in free-choice feeds containing 1440 or 150 g/ton was established in the supplemental approval under NADA 096-298, dated July 25, 2001, for BOVATEC (lasalocid sodium) (60 – 300 mg per head per day) in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) for increased rate of weight gain. Effectiveness for lasalocid in free-choice feeds containing 1088 g/ton was established in the supplemental approval under NADA 096-298, dated April 9, 2003, for BOVATEC (lasalocid sodium) (60 – 300 mg per head per day) in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) for increased rate of weight gain. No additional effectiveness data were required for approval of this supplement.

3. TARGET ANIMAL SAFETY:

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.

4. HUMAN SAFETY:

An FOI Summary was prepared with a supplemental application to NADA 96-298, approved August 6, 1982, providing for the use of lasalocid sodium 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 BOVATEC 91 (lasalocid sodium) to formulate various free-choice supplemental feeds, to provide lasalocid intakes of 60 to 300 mg/head/day on a nonconfined basis; therefore, the August 6, 1982, FOI Summary covers the toxicity, safe concentrations of residues, metabolism, total residues, and regulatory method aspects for the use of lasalocid for nonconfined cattle.

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 lasalocid sodium under the outlined conditions of use is safe and effective for the claims indicated in section 1 of this FOI Summary. The Agency has concluded that the toxicological and residue decisions made for the original approval in cattle also apply to changes described in the current supplement.

The Center for Veterinary Medicine has concluded that, for this product, BOVATEC, adequate directions for use by the layperson have been provided and the product will have over-the-counter (OTC) status. 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.

The drug is to be fed in Type C free-choice medicated feeds in accordance with section 1 of the FOI Summary and the Blue Bird labeling that is attached to this document.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Pursuant to 21 CFR 514.106 (b)(2), this supplemental NADA approval is regarded as a Category II supplemental change which did not require a reevaluation of safety and effectiveness data in the parent NADA.

No patents were submitted by the sponsor with this application.

6. ATTACHMENTS:

Table 1 Alpharma Formulated Free-Choice Lasalocid Mineral Type C Feed
Table 2 Alpharma Formulated Free-Choice Lasalocid Liquid Type C Feed
Table 3 Alpharma Formulated Free-Choice Lasalocid High Phosphorus Type C Feed

Facsimile Labeling is attached as indicated below:
Blue Bird Lasalocid – M Cattle Free Choice Mineral Supplement
Blue Bird Lasalocid – L Cattle Free Choice Liquid Supplement
Blue Bird Lasalocid Phos – M Cattle Free Choice Mineral

Table 1

Alpharma Formulated Free-Choice Lasalocid Mineral Type C Feed

Ingredient	**Percent**	**International feed No.**
Defluorinated phosphate (20.5% Ca, 18.5% P)	35.9	6-01-080
Sodium chloride (salt)	20.0	6-04-152
Calcium carbonate (38% Ca)	18.0	6-01-069
Cottonseed meal	10.0	5-01-621
Potassium chloride	3.0	6-03-755
Selenium premix (0.02 percent Se)[1]	3.0	. . . .
Dried cane molasses (46% Sugars)	2.5	4-04-695
Magnesium sulfate	1.7	6-02-758
Vitamin premix[1]	1.4	. . . .
Magnesium oxide (58% Mg)	1.2	6-02-756
Potassium sulfate	1.2	6-06-098
Trace mineral premix[1]	1.04	. . . .
Lasalocid Type A medicated article (68 g/lb)[2]	1.06	. . . .

[1] Content of vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

Table 2

Alpharma Formulated Free-Choice Lasalocid Liquid Type C Feed

Ingredient	**Percent**	**International feed No.**
Cane molasses	55.167	4-13-241
Condensed molasses fermentation solubles	24.00	N/A
50% Urea Solution (23% N)	12.00	N/A
Ammonium polyphosphate solution	1.00	6-08-42
Phosphoric acid (54%)	3.00	6-03-707
Xanthan gum	0.05	8-15-818
Water	4.00	N/A
Trace mineral premix[1]	0.50	N/A
Vitamin premix[1]	0.20	N/A
Lasalocid Type A medicated article (90.7 g/lb)[2]	0.083	N/A

[1] Content of these vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice liquid feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 150 g lasalocid per ton, use 1.652 lbs (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

Table 3

Alpharma Formulated Free-Choice Lasalocid High Phosphorus Type C Feed

Ingredient	**Percent**	**International feed No.**
Monocalcium phosphate (21% P)	57.50	6-01-082
Salt	17.55	6-04-152
Distillers dried grains w/ solubles	5.40	5-28-236
Dried cane molasses (46% sugars)	5.20	4-04-695
Potassium chloride	4.90	6-03-755
Trace mineral/vitamin premix[1]	3.35	. . . .
Calcium carbonate (38% Ca)	2.95	6-01-069
Mineral oil	1.05	8-03-123
Magnesium oxide (58% Mg)	1.00	6-02-756
Iron oxide (52% Fe)	0.10	6-02-431
Lasalocid Type A medicated article (68 g/lb)[2]	0.80	. . . .

[1] Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containging 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

SIGNATURE PAGE FOR THE
FREEDOM OF INFORMATION SUMMARY

NADA # N-096298-C-0348

SPONSOR Alpharma Inc.

NAME OF DRUG BOVATEC (Lasalocid Sodium)

	CONCURRENCE: (Signature-date)		CONCURRENCE WITH REVISIONS, IF REVISED
1.	Primary Reviewer HFV-126	Date	INITIAL
2.	Team Leader HFV-126	Date	INITIAL
3.	Acting Division Director HFV-120	Date	INITIAL
4.	Division Director HFV-150	Date	INITIAL
5.	QAT, HFV-107	Date	INITIAL
6.	Director, ONADE HFV-100	Date	INITIAL