

Approval Date: JUL 30 2004

## **FREEDOM OF INFORMATION SUMMARY**

**SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION**

**NADA 141-148**

**DECCOX (decoquinate) plus RUMENSIN (monensin sodium)**

**“To increase the feeding range of decoquinate to 12.9 to 90.8 g/ton”**

Sponsored by:

Alpharma Inc.

**1. GENERAL INFORMATION:**

- a. File Number: NADA 141-148
- b. Sponsor: Alpharma Inc.  
One Executive Drive  
P.O. Box 1399  
Fort Lee, NJ 07024  
  
Drug Labeler Code: 046573
- c. Established Names: Decoquate  
Monensin sodium
- d. Proprietary Names: DECCOX  
RUMENSIN
- e. Dosage Form: Type A medicated articles
- f. How Supplied: Type C medicated feed
- g. How Dispensed: OTC
- h. Amount of Active Ingredient: Decoquate: DECCOX 6 %  
Monensin: RUMENSIN 20, 30, 45, 60, 80, and 90.7 g/lb
- i. Route of Administration: Oral, *via* feed
- j. Species/Class: Cattle/fed in confinement for slaughter
- k. Recommended Dosage: Original Approval: Decoquate at 13.6 to 27.2 g/ton to deliver 22.7 mg/100 lb body weight per day plus monensin at 5 to 30 g/ton to deliver 50 to 360 mg per head per day
- l. Pharmacological Category: Decoquate: anticoccidial  
Monensin: ionophore growth promotant
- m. Indications: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and improved feed efficiency in cattle being fed in confinement for slaughter.
- n. Effect of Supplement: Provides for the expanded dose range of 12.9 to 90.8 grams per ton of feed for decoquate when used in combination with monensin sodium, and for revised Blue Bird labels.

**2. EFFECTIVENESS:**

The original approval for this combination was in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996. No further effectiveness data were required from the original approval as discussed in the parent NADA 141-148 FOI Summary approval dated November 16, 2000.

**3. TARGET ANIMAL SAFETY**

The original approval for this combination was in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996. No further target animal safety data were required from the original approval as discussed in the parent NADA 141-148 FOI Summary approval dated November 16, 2000.

**4. HUMAN SAFETY:**

The original approval for this combination was in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996. No further human food safety data were required from the original approval as discussed in the parent NADA 141-148 FOI Summary approval dated November 16, 2000. There is no withdrawal period for slaughter.

**5. AGENCY CONCLUSIONS:**

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the FFDCA and 21 CFR Part 514 of the implementing regulations. The data demonstrate that this combination of decoquinatate (12.9 to 90.2 g/ton) plus monensin (5 to 30 g/ton) is safe and effective for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and improved feed efficiency in cattle being fed in confinement for slaughter.

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

The drugs are to be fed in Type C medicated feeds in accordance with section 2 and 3 of the FOI Summary and the Blue Bird labeling that is attached to this document.

The Agency has concluded that this product may retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

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

**6. ATTACHMENTS:**

Facsimile Bluebird Labeling is attached as indicated below:

Type B Cattle Feed Medicated

Type C Complete Cattle Feed Medicated

**Bluebird DCX + MON  
Type B Cattle Feed  
Medicated**

For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and improved feed efficiency in cattle being fed in confinement for slaughter.

**Active Drug Ingredients<sup>1</sup>**

Decoquinatate..... 535.8 to 5,440 g/ton  
Monensin sodium..... 500 to 80,000 g/ton

**Guaranteed Analysis**

Crude protein, not less than..... %  
Crude fat, not less than..... %  
Crude fiber, not more than..... %  
Calcium, not less than ..... %  
Calcium, not more than..... %  
Phosphorus, not less than ..... %  
Potassium, not less than..... %  
Salt<sup>2</sup>, not less than ..... %  
Salt<sup>2</sup>, not more than ..... %  
Sodium<sup>3</sup>, not less than ..... %  
Sodium<sup>3</sup>, not more than ..... %

**Ingredients**

Ingredients as defined by AAFCO.

**Mixing Directions**

Mix this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete Type C medicated cattle feed containing 12.9 to 90.8 grams decoquinatate and 5 to 30 grams monensin (to provide 22.7 mg decoquinatate per 100 lb of body weight/day, 50 to 360 mg monensin/head/day). The Type C medicated feed is to be fed for the prevention of coccidiosis and improved feed efficiency during periods of exposure to coccidiosis or when it is likely to be a hazard. Feed only to cattle being fed in confinement for slaughter. Feed continuously as the sole ration. The following table provides examples of mixing and feeding rates.

Type B, grams/ton		Animal Wt. (lbs)	Lbs. Feed Per Head - Per Day	Lbs. Type B per Ton of Feed	Lbs. Non-medicated Feed per Ton	Type C, grams/ton	
Decoquinatate	Monensin					Decoquinatate	Monensin
1136	1000	500	10	40	1960	22.7	20
2271	2015	500	15	13.3	1986.7	15.1	13.4
1136	715	700	14	40	1960	22.7	14.3
2271	1430	700	21	13.3	1986.7	15.1	9.5

**Warning:** Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. When mixing and handling monensin use protective clothing, impervious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

**Caution:** Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle feed is safe only for use in cattle. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin may be fatal to cattle. Must be thoroughly mixed in feeds before use. Do not feed undiluted. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. Bentonite should not be used in decoquinatate feeds.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

Expiration Date: (30 days after date of manufacture)

<sup>1</sup> Actual label must bear the single concentration of each drug.

<sup>2</sup> If added.

<sup>3</sup> Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

**Bluebird DCX + MON  
Type C Complete Cattle Feed  
Medicated**

For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and improved feed efficiency in cattle being fed in confinement for slaughter.

**Active Drug Ingredients<sup>1</sup>**

Decoquinat..... 12.9 to 90.8 g/ton<sup>2</sup>  
Monensin sodium..... 5 to 30 g/ton<sup>2</sup>

**Guaranteed Analysis**

Crude protein, not less than..... %  
Crude fat, not less than..... %  
Crude fiber, not more than..... %  
Calcium, not less than..... %  
Calcium, not more than..... %  
Phosphorus, not less than..... %  
Potassium, not less than..... %  
Salt<sup>3</sup>, not less than..... %  
Salt<sup>3</sup>, not more than..... %  
Sodium<sup>4</sup>, not less than..... %  
Sodium<sup>4</sup>, not more than..... %

**Ingredients**

Ingredients as defined by AAFCO.

**Feeding Directions**

Feed only to cattle being fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 of mg decoquinat per 100 lb of body weight per day and 50 to 360 mg of monensin per head per day. Feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. The following table provides examples of feeding rates and amount of drug per ton of feed:

Animal Wt. (lbs.)	Feed Intake (% Body Wt)	Lbs. Feed Per Head /Day	Decoquinat (grams/ton)	Monensin, 100 mg/head/day (grams/ton)
500	1.5	7.5	30.3	26.7
	2.0	10.0	22.7	20.0
	3.0	15.0	15.1	13.3
	3.5	17.5	13.0	11.4
600	1.5	9.0	30.3	22.2
	2.0	12.0	22.7	16.7
	3.0	18.0	15.1	11.1
	3.5	21.0	13.0	9.5
700	1.5	10.5	30.3	19.0
	2.0	14.0	22.7	14.3
	3.0	21.0	15.1	9.5
	3.5	24.5	13.0	8.2
800	1.5	12.0	30.3	16.7
	2.0	16.0	22.7	12.5
	3.0	24.0	15.1	8.3
	3.5	28.0	13.0	7.1

**Warning**

Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle.

**Caution**

Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal. Monensin medicated cattle feed is safe only for use in cattle. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin may be fatal to cattle. Must be thoroughly mixed in feeds before use. Do not feed undiluted. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

Expiration Date: (30 days after date of manufacture)

<sup>1</sup> Actual label must bear the single concentration of each drug.

<sup>2</sup> Concentrations (grams per ton) must be such that feed delivers a total intake of 22.7 mg decoquinat per 100 pounds body weight per day and 50 to 360 mg monensin per head per day. Indicate in feeding directions amount of medicated feed to be consumed daily.

<sup>3</sup> If added.

<sup>4</sup> Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.