

Approval Date: December 16, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-147

DECCOX (decoquinat) plus CHLORMAX (chlortetracycline)

To provide Type B and C labeling with the revised decoquinat range of 12.9 to 90.8 g/ton and chlortetracycline range of 500 to 4000 g/ton in the Type C complete feed and decoquinat range of 90.9 to 535.7 g/ton and chlortetracycline range of 4000 to 20,000 g/ton in the Type C supplement feed.

Sponsored by:

Alpharma Inc.

1. GENERAL INFORMATION:

- a. File Number: NADA 141-147
- b. Sponsor: Alpharma Inc.
One Executive Drive
P.O. Box 1399
Fort Lee, NJ 07024

Drug Labeler Code: 046573
- c. Established Names: Decoquate
Chlortetracycline
- d. Proprietary Names: DECCOX
CHLORMAX
- 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 %
Chlortetracycline: CHLORMAX 50 g/lb
- i. Route of Administration: Oral, *via* feed
- j. Species/Class: Cattle/calves, beef and non-lactating dairy cattle
- 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 chlortetracycline at 500 to 1000 g/ton to deliver 1 g/100 lb body weight per day not to exceed 5 days.
- l. Pharmacological Category: Decoquate: anticoccidial
Chlortetracycline: antimicrobial
- m. Indications: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; for the treatment of bacterial enteritis caused by *Escherichia coli* and for bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.
- n. Effect of Supplement: To revise the Type B and C labeling with the revised decoquate range of 12.9 to 90.8 g/ton and chlortetracycline range of 500 to 4000 g/ton in the Type C complete feed and decoquate range of 90.9 to 535.7 g/ton and chlortetracycline range of 4000 to 20,000 g/ton in the Type C supplement feed.

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 141-147 FOI Summary approval dated September 29, 2000. The original approval was for feeding ranges for decoquinatate of 13.6 to 27.2 g/ton and chlortetracycline of 500 to 1000 g/ton. This supplement allows for the recent approved changes in the parent NADAs to be incorporated into the combination. A supplement to NADA 48-761 (AUREOMYCIN) approved January 24, 2002, allowed for increased feeding ranges of 500 to 4000 g/ton for Type C medicated complete feed and 4000 to 20,000 g/ton for Type C medicated feed top dress supplements. CHLORMAX and AUREOMYCIN were deemed equivalent July 9, 1996, by NAS/NRC DESI evaluation, so this approved feeding range is applicable to CHLORMAX (NADA 46-699) in this ADAA combination. The expanded feeding range of DECCOX was approved September 4, 2002, under NADA 39-417.

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 141-147 FOI Summary approval dated September 29, 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 141-147 FOI Summary approval dated September 29, 2000. There is a 24 hr withdrawal period for slaughter.

5. AGENCY CONCLUSIONS:

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512(d)(4) of the FFDCA and 21 CFR Part 514 of the implementing regulations. The data demonstrate that this combination of DECCOX (decoquinatate) (12.9 to 90.2 g/ton) plus CHLORMAX (chlortetracycline) (500 to 4000 g/ton) and DECCOX (decoquinatate) (90.9 to 535.7 g/ton) plus CHLORMAX (chlortetracycline) (4000 to 20,000 g/ton) is safe and effective for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* and for the treatment of bacterial enteritis caused by *Escherichia coli* and for bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

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.

In accordance with 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.

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:

Blue Bird DCX + CMX Type B Cattle Feed Medicated

Blue Bird DCX + CMX Type C Complete Cattle Feed Medicated

Blue Bird DCX + CMX Type C Cattle Supplement Medicated