Approval Date: December 16, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-185

DECCOX (decoquinate) plus AUREOMYCIN (chlortetracycline)

To provide for Type B and C labeling with the revised decoquinate 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 decoquinate 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 141-185
b. Sponsor:	Alpharma Inc. One Executive Drive P.O. Box 1399 Fort Lee, NJ 07024 Drug Labeler Code: 046573
c. Established Names:	Decoquinate Chlortetracycline
d. Proprietary Names:	DECCOX AUREOMYCIN
e. Dosage Form:	Type A medicated articles
f. How Supplied:	Type C medicated feed
g. How Dispensed	OTC
h. Amount of Active Ingredient	Decoquinate: DECCOX 6 % Chlortetracycline: AUREOMYCIN 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: Decoquinate 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:	Decoquinate: 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 decoquinate 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 decoquinate 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 141-185 FOI Summary approval dated March 15, 2002. The original approval was for feeding ranges for decoquinate 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. 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 141-185 FOI Summary approval dated March 15, 2002.

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 141-185 FOI Summary approval dated March 15, 2002. 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(d)(4) of the FFDCA and 21 CFR Part 514 of the implementing regulations. The data demonstrate that these combinations of decoquinate (12.9 to 90.2 g/ton) plus chlortetracycline (500 to 4000 g/ton) and decoquinate (90.9 to 535.7 g/ton) plus chlortetracycline (4000 to 20,000 g/ton) are 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 + Aureo Type B Cattle Feed Medicated

Blue Bird DCX + Aureo Type C Complete Cattle Feed Medicated

Blue Bird DCX + Aureo Type C Cattle Supplement Medicated