Approval Date: July 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:	Decoquinate 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	Decoquinate: 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: Decoquinate 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:	Decoquinate: 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 decoquinate 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 decoquinate (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