Date of Approval Letter: September 4, 2002

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 039-417

DECCOX® (decoquinate) Type A Medicated Article

"To provide for changes in the regulation (21 CFR 558.195) governing the use of decoquinate in cattle, sheep and goat feeds."

Sponsored by :

ALPHARMA, INC.

1. GENERAL INFORMATION

a.	File Number:	NADA 039-417
b.	Sponsor:	Alpharma Inc. One Executive Drive, P.O. Box 1399 Fort Lee, New Jersey 07024 Drug Labeler Code: 046573
c.	Established Name	decoquinate
d.	Proprietary Name:	DECCOX®
e.	Dosage Form:	Type A medicated article
f.	How Supplied:	50-lb bag
g.	How Dispensed:	OTC
h.	Amount of Active Ingredients:	27.2 grams per pound (6%)
i.	Route of Administration:	*per os,* mixed in feed
j.	Species/Class:	Ruminating and non-ruminating calves, including veal calves, and cattle, sheep, and goats
k.	Recommended Dosage:	22.7 mg/100 pounds bodyweight 12.9 to 90.8 g/ton (milk supplement and complete feed) 90.0 to 535.7 g/ton (top-dress)
l.	Pharmacological Category:	Anticoccidial
m.	Indications:	**Cattle:** for the prevention of coccidiosis in ruminating and non-ruminating calves, including veal calves, and cattle caused by *Eimeria bovis* and *E. zuernii.* **Sheep:** for the prevention of coccidiosis in young sheep caused by *E. ovinoidalis*, *E. crandallis, E. parva*, and *E. bakuensis*. **Goats:** for the prevention of coccidiosis in young goats caused by *E. christenseni* and *E. ninakohlyakimovae*.
n.	Effect of Supplement	To change 21 CFR 558.195 to revise the use levels to ranges of 12.9 to 90.8 g/ton for dry milk supplement and complete feed and 90.9 to 535.7 g/ton for top dress for cattle, sheep, and goat indications.

2. EFFECTIVENESS

No new effectiveness data are required for the approval of this supplement. The product effectiveness at a dose of 22.7 mg/100 lb bodyweight has been established in the original approval of NADA 039-417.

3. TARGET ANIMAL SAFETY

No new target animal safety data are required for the approval of this supplement. Target animal safety at a dose of 22.7 mg/100 lb bodyweight has been established in the original approval of NADA 039-417.

4. HUMAN SAFETY

No new human food safety data are required for the approval of this supplement. Residue data supporting the approval of this supplement are provided by reference to NADA 039-417.

5. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfies the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 CFR Part 514 of the implementing regulations for DECCOX® for use in cattle, sheep, and goats and allows for the revision of feed levels to ranges of 12.9 to 90.8 g/ton for dry milk supplement and complete feed and 90.9 to 535.7 g/ton for top dress.

There is reasonable certainty that the conditions of use, including directions on labeling, can and will be followed in practice. The agency has concluded that this product shall retain over-the-counter marketing status.

In accordance with 21 CFR 514.106(b)(2)(i), this is a category II change which did not require reevaluation of the safety or effectiveness data in the parent application.

Under 512(c)(2)(F)(iii) of the FFDCA, this supplemental approval for food-producing animals does not qualify for marketing exclusivity because the application does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

6. ATTACHMENTS

A. Blue Bird DECCOX® Type B Cattle Feed Medicated

B. Blue Bird DECCOX® Type B Sheep and Goat Feed Medicated

C. Blue Bird DECCOX® Type C Cattle Feed Supplements Medicated

D. Blue Bird DECCOX® Type C Sheep and Goat Feed Supplements Medicated

E. Blue Bird DECCOX® Type C Complete Cattle Feed Medicated

F. Blue Bird DECCOX® Type C Complete Sheep and Goat Feed Medicated

Applicable labels may be obtained by writing to the following:

Freedom of Information Staff (HFI-35)
Food and Drug Administration, Room 12A16
5600 Fishers Lane
Rockville, Maryland 20857