Date of Approval: July 19, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 012-350

CORID (amprolium) Type A Medicated Article 25%

"To allow for a broader range of concentrations of amprolium in the Type C medicated feed"

Sponsored by:
Merial Limited

1. GENERAL INFORMATION

A. File Number:	NADA 012-350
B. Sponsor:	Merial Ltd. 3239 Satellite Blvd., Bldg. 500 Duluth, GA 30096-4640 Drug Labeler Code: 050604
C. Established Name:	Amprolium
D. Proprietary Name:	CORID Type A Medicated Article 25%
E. Dosage Form:	Type A medicated article
F. How Supplied:	50 lb bags
G. How Dispensed:	Over-the-Counter (OTC)
H. Amount of Active Ingredients:	25% amprolium
I. Route of Administration:	Orally mixed in the feed or as a top dress
J. Species/Class:	Cattle/calves
K. Recommended Dosage:	Prevention – 5 mg/kg body weight daily for 21 days Treatment – 10 mg/kg body weight daily for 5 days
L. Pharmacological Category:	Anticoccidial
M. Indications:	As an aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves.
N. Effect of Supplement:	To allow a broader range of concentrations of amprolium in the Type C medicated feed from 0.05% to 1.25% to 0.0125% to 1.25% (113.5 to 11,350 g/ton) and update the Type A medicated article and the Type B and C medicated feed labeling.

2. EFFECTIVENESS

No further effectiveness data were required for the approval of this supplemental application.

The feeding range of amprolium in the Type C medicated feed as codified in 21 CFR 558.55 (0.05% to 1.25%) is too narrow to encompass all calves at the range of body weights and different possible dry matter intake levels. For example, the approved dosage for amprolium as an aid in the prevention of coccidiosis in calves is 5 mg/kg body weight (227.27 mg/100 lbs body weight). The dry matter intake (DMI) for calves can be as high as 4%. In order to treat a calf weighing 100 lbs when fed at a 4% DMI, 227.27 mg of amprolium must be added to 4 lbs of feed, resulting in a final concentration of 0.0125% amprolium. Therefore, the minimum allowable concentration of amprolium in Type C medicated feed is lowered from 0.05% to 0.0125% amprolium (113.5 g/ton).

3. TARGET ANIMAL SAFETY

No further target animal safety data were required for the approval of this supplemental application.

4. HUMAN FOOD SAFETY

No further human food safety data were required for this supplemental approval to the parent NADA 012-350 providing for use in calves dated December 21, 1973. The withdrawal period is 24 hours before slaughter and a withdrawal period has not been established for pre-ruminating calves.

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that the feeding concentration of amprolium in the Type C medicated feed may be widened to 0.0125% to 1.25% (113.5 to 11,350 g/ton) to allow appropriate dosing of all weights of calves at all DMI levels commonly fed.

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

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

No patent information was submitted with this application.

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

A. Type A Medicated Article

B. Amprolium Crumbles/Pellets Type B Medicated Feed Coccidiostat for Calves

C. Amprolium Crumbles/Pellets Type C Medicated Feed Coccidiostat for Calves