Date of Approval: January 19, 1999

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-060

DECCOX®-M (decoquinate) Medicated Powder for Whole Milk

"… for the prevention of coccidiosis in ruminating and non-ruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*."

Sponsored by

ALPHARMA INC.

I. GENERAL INFORMATION

NADA Number: 141-060

Sponsor: Alpharma Inc.
One Executive Drive
Fort Lee, New Jersey 07024

Established Name: decoquinate

Trade Name: DECCOX®-M (decoquinate) Medicated Powder for Whole Milk

Marketing Status: over-the-counter

Effect of NADA: This original NADA provides for the use of DECCOX®-M in whole milk fed to ruminating and nonruminating calves, including veal calves, for the prevention of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

II. INDICATIONS FOR USE

DECCOX®-M is indicated for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in ruminating and non-ruminating calves, including veal calves.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

A. Dosage Form: medicated powder containing 0.8% decoquinate.

B. Route of Administration: orally, via whole milk

C. Approved Dose: DECCOX®-M is to be added to whole milk at a rate to provide 22.7 mg decoquinate per 100 pounds of body weight daily (0.5 mg decoquinate per kg body weight) for at least 28 days during periods of exposure to coccidiosis or when experience indicates that coccidiosis is likely to be a hazard.

IV. EFFECTIVENESS

Data supporting the effectiveness of decoquinate for the prevention of coccidiosis in ruminating calves and cattle are summarized in the FOI SUMMARY for NADA 39-417 for DECCOX® Coccidiostat Type A Medicated Article (41 FR 53003; December 3, 1976). Data to support effectiveness in non-ruminating calves was included in a supplement to this NADA (56 FR 15498, April 17, 1991). Data to support the addition of veal calves to the label was presented in a separate supplement approved in April 1992.

This original NADA provides for use of decoquinate in the same classes of cattle and conditions of use in a different formulation (whole milk vs Type C feeds, including milk replacers) and does not require additional effectiveness data.

V. ANIMAL SAFETY

Data supporting the target animal safety of decoquinate for the prevention of coccidiosis in ruminating calves and cattle are summarized in the FOI SUMMARY for NADA 39-417 for DECCOX® Coccidiostat Type A Medicated Article (41 FR 53003; December 3, 1976). Data to support target animal safety in non-ruminating calves was included in a supplement to this NADA (56 FR:15498, April 17, 1991). Data to support the addition of veal calves to the label was presented in a separate supplement approved in April 1992.

This original NADA provides for use of decoquinate in the same classes of cattle and conditions of use in a different formulation (whole milk vs Type C feeds, including milk replacers) and does not require additional target animal safety data.

VI. HUMAN SAFETY

Data supporting the human food safety of DECCOX® Coccidiostat Type A Medicated Article are summarized in the FOI SUMMARY for NADA 39-417 (41 FR 53003; December 3, 1976).

Residue data to support the approval of decoquinate in non-ruminating calves was included in the supplemental approval for NADA 039-417, dated April 12, 1991 (56 FR 15498; April 12, 1991). Residue levels and the withdrawal time are not expected to be different when using DECCOX® in whole milk rather than in a milk replacer-based formulation.

Tolerances values for decoquinate of 1 ppm for skeletal muscle and 2 ppm for other tissues of chickens, cattle, and goats are established under 21 CFR 556.170.

Decoquinate is approved for cattle and calves at 22.7 mg/lb body weight/day (0.5 mg/kg) for at least 28 days in the feed and whole milk. No withdrawal period is required.

As part of the approval of this supplement, the Agency has taken the opportunity to update the human food safety information on this product and to codify an Acceptable Daily Intake (ADI) of 75 mcg/kg body weight/day under 21 CFR 556. This value is derived from the no observable effect level (NOEL) of 15 mg/kg body weight/day in a 12-week subchronic dog study and a safety factor of 200. The ADI is consistent with previous toxicity data submitted under NADA 39-417 and the conclusions of the summary report of the Committee for Veterinary Medicinal Products (CVMP) of the European Agency for the Evaluation of Medicinal Products.

VII. AGENCY CONCLUSIONS

The existing data in NADA 141-060 satisfy the requirements of Section 512 of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. Decoquinate when administered daily for at least 28 days in whole milk and fed at the rate of 22.7 mg/lb body weight (0.5 mg/kg) to ruminating and non-ruminating calves is safe and effective for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

As described in Section VI, the tolerance for residues of decoquinate is codified as 1 ppm in skeletal muscle of cattle and as 2 ppm in other edible tissues and the ADI is codified at 75 mcg/kg body weight/day under 21 CFR 556.170. Decoquinate is approved for use in calves and cattle at 22.7 mg/lb body weight/day (0.5mg/kg) for at least 28 days with no withdrawal period required.

Adequate directions have been written for the layman and the conditions for mixing and use prescribed on the labeling are likely to be followed by the producer in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product can be approved with over-the-counter marketing status.

In accordance with 21 CFR 25.33(a)(3), this action qualifies for a categorical exclusion from the requirement to prepare an environmental assessment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(ii) of the FFDCA, this 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 and conducted or sponsored by the applicant.

DECCOX®-M is not under any unexpired U.S. patents.

VIII. APPROVED LABELING

Facsimile labeling components are attached for the 5-, 10-, and 50-pound bags.