FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

NADA: 115-581

Sponsor: MoorMan's, Inc.
1000 North 30th Street
Post Office Box C1
Quincy, IL 62305-3115

Established Name: Monensin Sodium

Trade Name: Rumensin®

Marketing Status: OTC

Effect of Supplement: This supplement provides for the addition of the claim "for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*" to MoorMan's Type C monensin medicated free-choice protein-mineral blocks (MoorMan's Mintrate Blonde Block RU and MoorMan's Mintrate Red Block RU).

II. INDICATIONS FOR USE:

For increased rate of weight gain; and prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) on pasture which may require supplemental feed.

III. DOSAGE FORM, DOSAGE, AND ADMINISTRATION:

A. *Dosage Form*: Rumensin® is a Type A Medicated Article available in 50-lb bags containing 80 g monensin sodium/lb. The monensin medicated blocks are Type C free-choice feeds containing 300 g monensin sodium/ton.

B. *Route of Administration*: Orally, as a free-choice Type C medicated protein-mineral feed block.

C. *Recommended Dosage:* Feed continuously on a free choice basis at the rate of 50 to 200 milligrams monensin per head per day.

Note: MoorMan's has authorization to reference data and information in Elanco's NADA 095-735 for monensin to support the safety and effectiveness of their products.

IV. EFFECTIVENESS:

Data supporting the effectiveness of previously approved indications are discussed in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 22, 1990, December 16, 1998, and July 31, 2000). No new data were required for the approval of this supplement.

V. SAFETY FOR THE TARGET SPECIES:

Data supporting the target animal safety of Rumensin® (monensin) Type A Medicated Article are summarized in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 23, 1995, July 15, 1996, and July 31, 2000). No additional data were required for approval of this supplement.

VI. HUMAN SAFETY:

Data supporting the human food safety of Rumensin® (monensin) Type A Medicated Article are summarized in the original FOI Summary for NADA 095-735. The acceptable daily intake (ADI) for total residues of monensin is 12.5 micrograms per kilogram of body weight, while the tolerance is 0.05 part per million for negligible residues of monensin in edible tissues of cattle (21 CFR 556.420).

VII. AGENCY CONCLUSIONS:

The data submitted in support of this 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 50-200 mg monensin/head/day when used in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) is safe and effective for the supplemental claim of prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the layman have been provided and the product will retain its over-the-counter marketing status.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental 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.

VIII. LABELING

The following labeling is attached:

1. MoorMan's® Mintrate® Blonde Block RU
2. MoorMan's® Mintrate® Blonde Red RU