DATE OF APPROVAL LETTER: JUL 7 2000

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 95-735

Free Choice Monensin Mineral Granules
Type C Medicated Feed

"For the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*"

Sponsored by:
ELANCO ANIMAL HEALTH

I. GENERAL INFORMATION

NADA Number:	095-735
Sponsor:	Elanco Animal Health A Division of Eli Lilly and Co. Lilly Corporate Center Indianapolis, Indiana, 46285
Established Name:	monensin sodium
Trade Name:	RUMENSIN® 80 Type A Medicated Article (Free Choice Monensin Mineral Granules Type C Medicated Feed)
Marketing Status:	Over-the-counter (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 the Free Choice Monensin Mineral Granules Type C Medicated Feed label.

II. INDICATIONS FOR USE

For increased rate of weight gain and the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

A. *Dosage Form*: RUMENSIN® 80 is a Type A Medicated Article available in 50-lb bags containing 80 g monensin sodium/lb. The Monensin Mineral Granule is a Type C Free Choice feed containing 1620 g monensin sodium/ton.

B. *Route of Administration*: Orally, as a mineral supplement

C. *Recommended Dosage:* Feed continuously on a free choice basis at the rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 mg/hd/day.

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, and December 16, 1998). No new data were required for the approval of this supplement.

V. TARGET ANIMAL SAFETY

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

VI. HUMAN FOOD SAFETY

Data supporting the human food safety of RUMENSIN® 80 Type A Medicated Article are summarized in the original FOI Summary for NADA 095-735.

VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental application satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations to enable FDA to revise 21 CFR 558.355(f)(3)(x) to provide for the safe and effective use of Monensin Type A medicated article to make free choice mineral granules Type C medicated feeds for the prevention and control of coccidiosis and increased rate of weight gain in pasture cattle.

A tolerance of 0.05 ppm for negligible residues of monensin in the edible tissues of cattle and the ADI of 12.5 mcg/kg bw/day are codified at 21 CFR 556.420. A withdrawal time before slaughter is not required.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

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

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

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

RUMENSIN® 80 Type A Medicated Article is under U.S. patent numbers:

Patent Number	Expiration Date
4366168	September 21, 2001
4405609	January 22, 2001
4468380	August 28, 2001
4764534	August 16, 2005

VIII. APPROVED LABELING (Attached)

1. Type C Bluebird labeling
2. Type A Medicated Article labeling