

Date of Approval: DEC 12 2008

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 095-735

**RUMENSIN 80
(monensin sodium)**

“To provide a technical amendment to 21 CFR 558.355(f)(3)(vii) and a revision to the Type C medicated feed label for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in feedlot cattle.”

SPONSORED BY:

ELANCO ANIMAL HEALTH

1. GENERAL INFORMATION:

- a. File Number: NADA 095-735
- b. Sponsor: Elanco Animal Health
A Division of Eli Lilly & Co.
Lilly Corporate Center
Indianapolis, IN 46285
- Drug Labeler Code: 000986
- c. Established Name: Monensin sodium
- d. Proprietary Name: RUMENSIN 80
- e. Dosage Form: Type A medicated article
- f. How Supplied: 50 pound bag
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 80 g monensin sodium/lb
- i. Route of Administration: Oral, in feed
- j. Species/Class: Bovine/feedlot cattle
- k. Recommended Dosage: For improved feed efficiency: Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 360 mg/hd/day. [21 CFR 558.355(f)(3)(i)]
- For the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*: Feed continuously at the rate of 0.14 to 0.42 mg/lb bw/day, depending on severity of challenge, up to a maximum of 360 g/hd/day. [21 CFR 558.355(f)(3)(vii)]
- l. Pharmacological Category: Production drug/anticoccidial
- m. Indications: For improved feed efficiency and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

n. Effect of Supplement:

To provide a technical amendment to 21 CFR 558.355(f)(3)(vii). The improved feed efficiency claim will be removed from 21 CFR 558.355(f)(3)(vii) and remain separately codified as it appears in 21 CFR 558.355(f)(3)(i). To provide for a revision to the Type C medicated feed label for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in feedlot cattle, changing the concentration of active drug ingredient from 10-200 g/ton of monensin to the correct level of 10 to 30 g/ton of monensin

2. EFFECTIVENESS:

Effectiveness data were generated in NADA 095-735 (approved December 16, 1975). No further effectiveness data were required.

3. TARGET ANIMAL SAFETY:

Target animal safety data were generated NADA 095-735 (approved December 16, 1975). No further target animal safety data were required.

4. HUMAN SAFETY:

Human safety data were generated in NADA 095-735 (approved December 16, 1975). No further human food safety data were required.

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 and 21 CFR Part 514 of the implementing regulations. The information provided supports the technical amendment of 21 CFR 558.355(f)(3)(vii) for RUMENSIN 80 and the revision of the Type C medicated feed label for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in feedlot cattle.

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

In accordance with 21 CFR 514.106(b)(1)(v), this is a Category I change.

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

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

Monensin Type C medicated feed label for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in feedlot cattle.

NET WEIGHT ON BAG OR BULK

MONENSIN TYPE C MEDICATED FEED

FEEDLOT CATTLE (CATTLE MAINTAINED IN CONFINEMENT FOR SLAUGHTER)

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

ACTIVE DRUG INGREDIENT

Monensin.....10 to 30 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than.....%
Non-Protein Nitrogen (NPN)¹, not more than.....%
Crude Fat, not less than.....%
Crude Fiber, not more than.....%
Calcium, not less than.....%
Calcium, not more than.....%
Phosphorus, not less than.....%
Salt², not less than.....%
Salt², not more than.....%
Sodium³, not less than.....%
Sodium³, not more than.....%
Potassium, not less than.....%
Vitamin A^{2,4}, not less than..... I.U./lb

¹When added.

²If added.

³Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

⁴Other than precursors of Vitamin A.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed continuously as the sole ration to cattle to provide 0.14 to 0.42 mg monensin/lb. bodyweight, depending upon severity of challenge, up to a maximum of 360 mg monensin/hd/day.

CAUTION: Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal. Monensin medicated cattle feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

When mixing and handling monensin, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

WARNING: Do not feed to lactating dairy cows. A withdrawal time has not been established in pre-ruminating calves. Do not use in calves processed for veal.

MANUFACTURED BY:
Bluebird Feed Mill
Anytown, IN 12345

Expiration Date: (30 days after manufacture)
Lot Number:_____