Approval Date: January 14, 2005

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-192

RALGRO LA
(Zeranol)

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Schering-Plough Animal Health Corp.
1095 Morris Ave.
Union, NJ 07083

FREEDOM OF INFORMATION SUMMARY

RALGRO LA
Ear Implant for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

1. GENERAL INFORMATION:

a. File Number:	NADA 141-192
b. Sponsor:	Schering-Plough Animal Health Corp. 1095 Morris Ave. Union, NJ 07083 Drug Labeler Code: 000061
c. Established Name:	Zeranol
d. Propriety Name:	RALGRO LA
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.2680
f. How Supplied:	Each carton contains ten 10-dose strip cartridges (138 mg dose). Each 138 mg dose consists of one 18 mg pellet of zeranol and six 20 mg pellets of controlled-release zeranol.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	138 mg zeranol in a long-acting formulation.
i. Route of Administration:	Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
j. Species/Class:	Pasture cattle (slaughter, stocker, and feeder steers and heifers).
k. Recommended Dosage:	One implant containing 138 mg zeranol.
l. Pharmacological Category:	Steroid hormone.
m. Indications:	For increased rate of weight gain for up to 210 days in pasture cattle (slaughter, stocker, and feeder steers and heifers).

n. Effect of Supplement:	This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

2. DRUG EFFECTIVENESS:

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summary for the parent new animal drug application for RALGRO LA (NADA 141192).

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summary for the parent new animal drug application for RALGRO LA (NADA 141192).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summary for the parent new animal drug application for RALGRO LA (NADA 141192).

5. AGENCY CONCLUSIONS:

The information submitted in support of this NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instructions in plain language. The drug is not a controlled substance. The product's status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

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

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.

No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

RALGRO LA 10 10-Dose Strip Cartridge Carton Label (RALOGUN LA Pellet Injector)
RALGRO LA Strip Cartridge Package Insert (RALOGUN LA Pellet Injector)