

Approval Date: JAN 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)

### I. 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.

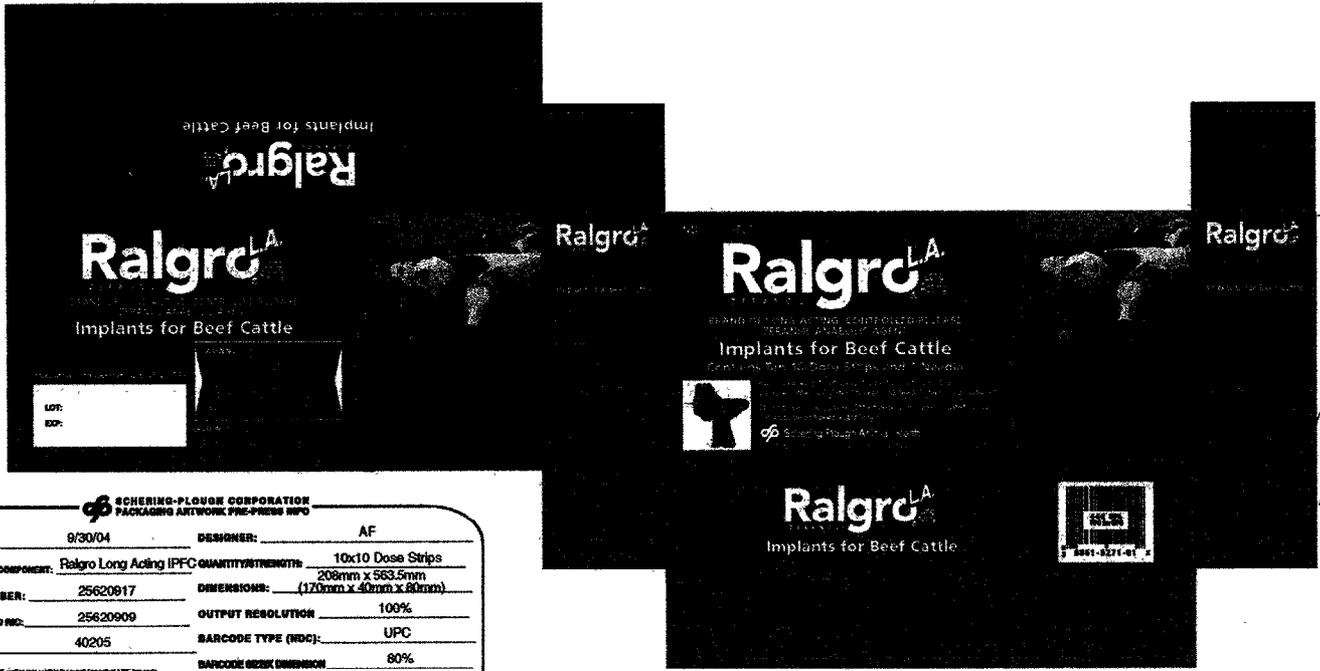
No patent information was submitted by the sponsor with this application.

**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)

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**SCHERING-PLOUGH CORPORATION**  
PACKAGING ARTWORK PRE-PRESS INFO

DATE: 9/30/04      DESIGNER: AF

PRODUCT/COMPONENT: Ralgron Long Acting IPFC      QUANTITY/STRENGTH: 10x10 Dose Strips

RIC NUMBER: 25620917      DIMENSIONS: 208mm x 563.5mm  
(170mm x 40mm x 80mm)

AFFECTED PIC: 25620909      OUTPUT RESOLUTION: 100%

LT#: 40205      BARCODE TYPE (NDC): UPC

BARCODE BEZEL DIMENSION: 80%

HUMAN-READABLE REQUIRED: YES  NO

FULL NUMBER (STY, CHARACTER) - NDC: 0061-5271-01 X

NOTE: For GTN - Package Level Indicator cut at 0 (zero).

FOR CUSTOMER APPROVALS OR SIGNATURES/INITIALS, PLEASE PRINT OR SIGN ON TUCK FLAPS OR BLUE SIDES, AS PER APPROVED ART.

AND OTHER: Supplier responsible for verifying actual LINE for each represented by 'XY' with applicable label based on process requirements in accordance with LSC standards. Minimum acceptance criteria is grade 'C' based on ISO 9002:2001 'the Code-Print Quality Guidelines'

SEE COMMENTS: ELEM, Temp & Unit (Unit) (Do not use) used for Schering-Plough Inventory Inspection for approval. Color Standards must be approved by Schering-Plough.

FOOTNOTES: Shall be provided to the Labeling Control Analyst for approval. Prints must be approved by Schering-Plough prior to printing. The supplier is not allowed to make any changes without written approval by Schering-Plough.

**PACKAGING COMPONENT APPROVAL**

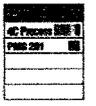
SUBMISSION # **2**

*EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BEZEL.*

	APPROVED	NOT APPROVED	DATE
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COPY EDITOR	<input type="checkbox"/>	<input type="checkbox"/>	_____
MEDICAL	<input type="checkbox"/>	<input type="checkbox"/>	_____
TRADEMARKS	<input type="checkbox"/>	<input type="checkbox"/>	_____
PATENTS	<input type="checkbox"/>	<input type="checkbox"/>	_____
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REGULATORY	<input type="checkbox"/>	<input type="checkbox"/>	_____

ART USE DATE: \_\_\_\_\_ INV LOCATION: \_\_\_\_\_

SQA APPROVAL VERIFIED: \_\_\_\_\_ DATE: \_\_\_\_\_



563.5

# RALGRO<sup>®</sup> LA

(long-acting, controlled-release zeranol)

## Implants for Beef Cattle

**CAUTION:** Do not use in bulls or heifers intended for reproduction or dairy animals. Edema of the vulva and udder, teat elongation, rectal and vaginal prolapse, and signs of estrus may occur when heifers are implanted.

**INDICATION FOR USE:** For increased rate of weight gain for up to 210 days in pasture cattle (slaughter, stocker, and feeder steers and heifers). Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DESCRIPTION:** Each dose is composed of one 18-mg pellet of zeranol and six 20-mg pellets of controlled-release zeranol. A single pull of the implant device trigger delivers the proper 138-mg dose.

**DOSAGE:** 138 mg of zeranol in a long-acting formulation.\*

**STORAGE:** RALGRO<sup>®</sup> LA implants are stable when stored at room temperature up to 25°C (77°F).

**WARNING: DO NOT ATTEMPT TO SALVAGE IMPLANT SITE FOR HUMAN OR ANIMAL FOOD. IMPLANT PELLETS IN THE EAR ONLY. ANY OTHER LOCATION IS IN VIOLATION OF FEDERAL LAW.**

**A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.**

\*In a clinical study evaluating the effect of 58 mg, 98 mg, and 138 mg of RALGRO LA on weight gain in steers, 138 mg gave the highest response but was not statistically different from 98 mg, and both were superior to 58 mg.

Manufactured by a nonsterilizing process.

**RESTRICTED DRUG (CALIFORNIA), USE ONLY AS DIRECTED.**

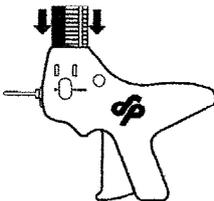
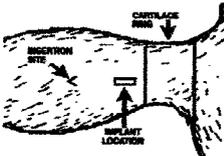
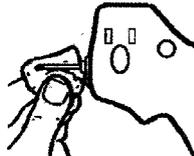
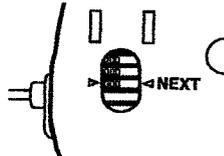
 Schering-Plough Animal Health  
Union, NJ 07083 USA

This product may not be marketed or used in Ireland or elsewhere in the EU.  
Made in Ireland.

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# DIRECTIONS

Use the following procedure for administering RALGRO® LA implants with the RALOGUN® LA PELLETT INJECTOR:

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
 <p><b>STEP 1:</b> Each chamber of the plastic strip cartridge contains a full 138-mg dose of RALGRO® LA. Insert the strip cartridge into the top of the RALOGUN® LA injector. Insert until it is even with the top of the injector. Either end of the strip cartridge can be inserted.</p>	 <p><b>STEP 2:</b> After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site.</p> <p><b>NOTE:</b> Always use a sharp needle. A dull needle tears tissue and makes proper implanting difficult and may lead to infection.</p>	 <p><b>STEP 3:</b> The implant site is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a spot toward the tip of the ear and at least a needle's length away from the intended deposition site.</p>	 <p><b>STEP 4:</b> Insert needle into ear and squeeze the trigger of the injector to deliver a full dose of RALGRO® LA. Keep trigger depressed while withdrawing the needle to be sure that the implant pellets stay in place. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear. Release the trigger and the RALOGUN® LA is automatically ready to administer the next dose.</p>	 <p><b>STEP 5:</b> Wipe needle with cotton or gauze moistened with alcohol or other disinfectant. Do not dip needle in solution because solution clinging to inside of the needle will cause plugging of needle.</p>	 <p><b>STEP 6:</b> Check in the window on the side of the RALOGUN® LA injector to ensure that the next dose of RALGRO® LA is properly aligned with the arrows that indicate NEXT dose.</p>