Approval Date: October 28, 2004

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

# NADA 140-897

## REVALOR–S, REVALOR-IS, and REVALOR-G
## Trenbolone Acetate and Estradiol

**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:**

**Intervet, Inc.**
**29160 Intervet Lane**
**P.O. Box 318**
**Millsboro, DE 19966**

**FREEDOM OF INFORMATION SUMMARY**

REVALOR–S and REVALOR-IS
Ear Implant for Steers Fed in Confinement for Slaughter

REVALOR-G
Ear Implant for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

## *1. GENERAL INFORMATION:*

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| a. File Number: | NADA 140-897 |
| b. Sponsor: | Intervet, Inc.<br>29160 Intervet Lane<br>P.O. Box 318<br>Millsboro, DE 19966<br>Drug Labeler Code: 057926 |
| c. Established Names: | Trenbolone Acetate and Estradiol |
| d. Propriety Names: | REVALOR–S<br>REVALOR-IS<br>REVALOR-G |
| e. Dosage Form: | Implantation (ear implant) as per 21 CFR 522.2477 |

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| f. How Supplied: | REVALOR-S: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 120 mg trenbolone acetate and 24 mg estradiol.<br><br>REVALOR-IS: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 80 mg trenbolone acetate and 16 mg estradiol.<br><br>REVALOR-G: Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 40 mg trenbolone acetate and 8 mg estradiol. |
| g. How Dispensed: | OTC |
| h. Amount of Active Ingredients: | REVALOR-S:<br>120 mg trenbolone acetate.<br>24 mg estradiol.<br><br>REVALOR-IS:<br>80 mg trenbolone acetate.<br>16 mg estradiol.<br><br>REVALOR-G:<br>40 mg trenbolone acetate.<br>8 mg estradiol. |
| 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: | REVALOR-S and REVALOR-IS: Steers fed in confinement for slaughter.<br><br>REVALOR-G: Pasture cattle (slaughter, stocker, and feeder steers and heifers). |

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| k. Recommended Dosage: | REVALOR-S: One implant containing 120 mg trenbolone acetate and 24 mg estradiol.<br><br>REVALOR-IS: One implant containing 80 mg trenbolone acetate and 16 mg estradiol.<br><br>REVALOR-G: One implant containing 40 mg trenbolone acetate and 8 mg estradiol |
| l. Pharmacological Category: | Steroid hormones |
| m. Indications: | REVALOR-S: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.<br><br>REVALOR-IS: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.<br><br>REVALOR-G: Increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers) in a slow-release delivery system. |
| 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) Summaries for the parent new animal drug application for REVALOR-S, REVALOR-IS, and REVALOR-G (NADA 140897).

***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) Summaries for the parent new animal drug application for REVALOR-S, REVALOR-IS, and REVALOR-G (NADA 140897).

## *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) Summaries for the parent new animal drug application for REVALOR-S, REVALOR-IS, and REVALOR-G (NADA 140897).

## *5. AGENCY CONCLUSIONS:*

The information 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 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 these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' 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:

REVALOR-S Package Insert
REVALOR-S Box Label
REVALOR-S Carton Label
REVALOR-S Shipping Container Label
REVALOR-IS Package Insert
REVALOR-IS Box Label
REVALOR-IS Carton Label
REVALOR-IS Shipping Container Label
REVALOR-G Package Insert
REVALOR-G Box Label
REVALOR-G Carton Label
REVALOR-G Shipping Container Label