Approval Date: January 14, 2005

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

# ANADA 200-346

## COMPONENT TE-200
## (trenbolone acetate and estradiol)

**Indications for use: For increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.**

**Sponsored by:**

**Ivy Laboratories,**
**Div. of Ivy Animal Health, Inc.**
**8857 Bond Street**
**Overland Park, KS 66214**

# FREEDOM OF INFORMATION SUMMARY

## *1. GENERAL INFORMATION:*

| | |
|---|---|
| a. File Number: | ANADA 200-346 |
| b. Sponsor: | Ivy Laboratories,<br>Div. of Ivy Animal Health, Inc.<br>8857 Bond Street<br>Overland Park, KS 66214<br><br>Drug Labeler Code: 021641 |
| c. Established Names: | Trenbolone acetate and estradiol |
| d. Proprietary Name: | COMPONENT TE-200 |
| e. Dosage Form: | Implantation (ear implant) |
| f. How Supplied: | As an implant made up of 10 pellets with each pellet containing 20 mg trenbolone acetate and 2 mg estradiol. One cartridge belt holds 20 implants. |
| g. How Dispensed: | OTC |
| h. Amount of Active Ingredients: | Trenbolone acetate: 200mg trenbolone acetate activity.<br>Estradiol: 20 mg estradiol activity. |
| i. Route of Administration: | Subcutaneous ear implant |
| j. Species/Class: | Steers and heifers fed in confinement for slaughter |
| k. Recommended Dosage: | One implant containing 200 mg trenbolone acetate and 20 mg estradiol per animal. |
| l. Pharmacological Category: | Steroid hormones [a natural occurring estrogen, estradiol and a synthetic testosterone, trenbolone acetate]. |
| m. Indications: | For increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter. |
| n. Pioneer Product: | REVALOR-200; trenbolone acetate and estradiol; NADA 140-992; Intervet, Inc. |

o. Effect of Supplement: This supplement provides for the addition of heifers to the label of Ivy Laboratories' approved product COMPONENT TE-200 (trenbolone acetate and estradiol). The indications are for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.

## *2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:*

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Ivy Laboratories, Div. of Ivy Animal Health, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product COMPONENT TE-200. The generic product is administered as an implant, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, REVALOR-200 (trenbolone acetate and estradiol), the subject of Intervet, Inc. (NADA 140-992), was approved for use in heifers on December 6, 2001.

## *3. HUMAN SAFETY:*

- **Tolerances for Residues:**

  The tolerance established for the pioneer product applies to the generic product. A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed (21 CFR 556.739). The acceptable daily intake (ADI) for total residues of trenbolone is 0.4 micrograms per kilogram of body weight per day (21 CFR 556.739).

  Estradiol is regulated under 21 CFR 556.240 on the basis of allowable incremental increases. The allowable incremental increases established for the pioneer product apply to the generic product. No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in the uncooked edible tissues of heifer, steers, and calves in excess of the following increments above the

concentrations of estradiol naturally present in untreated animals: 120 ppt for muscle, 480 ppt for fat, 360 ppt for kidney, and 240 ppt for liver.

- **Withdrawal Times:**

  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal time is zero days.

- **Regulatory Method for Residues:**

  A regulatory method is not required because the generic product is assigned a zero withdrawal.

## *4. AGENCY CONCLUSIONS:*

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that COMPONENT TE-200 (trenbolone acetate and estradiol), when used under its proposed conditions of use, is safe and effective for its labeled indications.

## *5. ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-346:
COMPONENT TE-200
Box Label – box of 5 cartridge belts of 20 implants each (100 doses)
Foil Pouch (Front)
Foil Pouch (Back)
Cartridge Label – 1 cartridge with 20 implants (20 doses)
Package Insert (Front)
Package Insert (Back)

Pioneer Labeling for NADA 140-992:
REVALOR-200
Box Label – box of 10 x 10 cartridge implants (100 doses) (2 sides)
Box Label – box of 10 x 100 cartridge implants (1000 doses)
Box Label – box of 4 x 1000 cartridge implants (4000 doses)
Cartridge Label– 1 cartridge with 10 implants (10 doses)
Package Insert