Approval Date: October 28, 2004

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

# ANADA 200-346

**COMPONENT TE-200**
**Trenbolone Acetate and Estradiol**

**COMPONENT TE-200 with TYLAN**
**Trenbolone Acetate and Estradiol with Tylosin**

**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:**

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

**FREEDOM OF INFORMATION SUMMARY**

COMPONENT TE-200 and COMPONENT TE-200 with TYLAN
Ear Implants for Steers Fed in Confinement for Slaughter

## *1. GENERAL INFORMATION:*

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|---|---|
| a. File Number: | ANADA 200-346 |
| b. Sponsor: | Ivy Laboratories<br>Division of Ivy Animal Health, Inc.<br>8857 Bond Street<br>Overland Park, KS 66214<br>Drug Labeler Code: 021641 |
| c. Established Names: | Trenbolone Acetate and Estradiol<br>Trenbolone Acetate and Estradiol with Tylosin |
| d. Propriety Names: | COMPONENT TE-200,<br>COMPONENT TE-200 with TYLAN |
| e. Dosage Form: | Implantation (ear implant) as per 21 CFR 522.2477 |
| f. How Supplied: | COMPONENT TE-200: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 200 mg and estradiol 20 mg.<br><br>COMPONENT TE-200 with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 200 mg and estradiol 20 mg with 29 mg tylosin tartrate as a local antibacterial. |
| g. How Dispensed: | OTC |

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|---|---|
| h. Amount of Active Ingredients: | COMPONENT TE-200:<br>200 mg trenbolone acetate.<br>20 mg estradiol.<br><br>COMPONENT TE-200 with TYLAN:<br>200 mg trenbolone acetate.<br>20 mg estradiol.<br>29 mg tylosin tartrate. |
| 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: | Steers Fed in Confinement for Slaughter |
| k. Recommended Dosage: | COMPONENT TE-200: One implant containing 200 mg trenbolone acetate and 20 mg estradiol.<br><br>COMPONENT TE-200 with TYLAN: One implant containing 200 mg trenbolone acetate and 20 mg estradiol with 29 mg tylosin tartrate. |
| l. Pharmacological Category: | Steroid hormone, anti-bacterial |
| m. Indications: | COMPONENT TE-200 and COMPONENT TE-200 with TYLAN: For increased rate of weight gain and improved feed efficiency. |
| 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 abbreviated new animal drug applications for COMPONENT TE-200 and COMPONENT TE-200 with TYLAN (ANADA 200346).

### *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 abbreviated new animal drug applications for COMPONENT TE-200 and COMPONENT TE-200 with TYLAN (ANADA 200346).

### *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 abbreviated new animal drug applications for COMPONENT TE-200 and COMPONENT TE-200 with TYLAN (ANADA 200346).

### *5. AGENCY CONCLUSIONS:*

The information submitted in support of this ANADA 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.

COMPONENT TE-200 with TYLAN is under the following US patent number:

| U.S. Patent Number | Date of Expiration |
|---|---|
| 5,874,098 | May 28, 2017 |

## *6. ATTACHMENTS:*

Facsimile Labeling is attached as indicated below:

COMPONENT TE-200 Carton Label
COMPONENT TE-200 Foil Pouch (Front)
COMPONENT TE-200 Foil Pouch (Back)
COMPONENT TE-200 Package Insert
COMPONENT TE-200 with TYLAN Carton Label
COMPONENT TE-200 with TYLAN Foil Pouch (Front)
COMPONENT TE-200 with TYLAN Foil Pouch (Back)
COMPONENT TE-200 with TYLAN Package Insert