

Approval Date: April 18, 2003

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION

ANADA 200-346

Trenbolone Acetate and Estradiol, and Tylosin Tartrate
(COMPONENT[®] TE-H WITH TYLAN[®])

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

**Supplemental approval to provide for the addition
of a tylosin tartrate pellet as a local antibacterial
to Component[®] TE-H**

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

Component[®] TE-H with Tylan[®] Ear Implant for Heifers Fed in Confinement for Slaughter

1. GENERAL INFORMATION

- a. File Number:** ANADA 200-346
- b. Sponsor:** Ivy Laboratories
Division of Ivy Animal Health, Inc.
8857 Bond Street
Overland Park, KS 66214
Drug Labeler Code: 021641
- c. Established Names:** Trenbolone acetate and estradiol, and tylosin tartrate
- d. Propriety Names:** Component[®] TE-H with Tylan[®]
- e. Dosage Form:** Implantation (ear implant) as per 21 CFR 522.2477.
- f. How Supplied:** As an implant made up of 8 pellets with 7 pellets each containing 20 mg trenbolone acetate and 2 mg estradiol and 1 pellet containing 29 mg tylosin tartrate
- g. How Dispensed:** OTC
- h. Amount of Active Ingredients:** Trenbolone acetate: 140 mg trenbolone acetate activity.
Estradiol: 14 mg estradiol activity.
Tylosin tartrate: 29 mg tylosin tartrate activity.
- i. Route of Administration:** Subcutaneous ear implant
- j. Species/Class:** Heifers fed in confinement for slaughter
- k. Recommended Dosage:** One implant containing 140 mg trenbolone acetate, 14 mg estradiol, and 29 mg tylosin tartrate per animal.
- l. Pharmacological Category:** Steroid hormone and antibacterial
- m. Indications:** For increased rate of weight gain and improved feed efficiency for heifers fed in confinement for slaughter.

n. Effect of Supplement:

This supplement provides for the addition of a tylosin tartrate pellet as a local antibacterial to Component[®] TE-H.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

The effectiveness requirement for this supplemental new animal drug application, with the indication for use and dosage as given in Section 1 above, is met by utilizing the information contained in the Freedom of Information (FOI) Summary for the abbreviated new animal drug application for Component[®] TE-H (ANADA 200-346) which was approved September 27, 2002, and contains adequate data from a well-controlled investigation demonstrating bioequivalence of Component[®] TE-H to the pioneer drug, Revalor[®]-H, as well as by having conducted the additional adequate and well-controlled study included in this supplemental application.

Pivotal Study:

A study was conducted by William Barton, CAVL, Inc, Amarillo, TX to evaluate the effectiveness of Component[®] TE-H with Tylan[®] (140 mg trenbolone acetate and 14 mg estradiol (7 pellets), and 29 mg tylosin tartrate (1 pellet)) to lower the incidence of ear abscess formation. An implant site abscess induction model was developed to reliably create a high abscess rate in test animals. This model was used to test the ability of a tylosin tartrate pellet to reduce implant site abscess incidence in animals expected to develop an ear abscess. In the study, 40 beef heifers were subjected to the abscess-inducing culture at the same time they were implanted with either Component[®] TE-H with a Tylan[®] pellet or Component[®] TE-H alone. Implant sites were observed at regular intervals up to 35 days following implantation. Abscess rate at each time point was significantly lower ($P < 0.0001$) in animals treated with Component[®] TE-H with a Tylan[®] pellet compared to animals treated with Component[®] TE-H alone, with the maximum incidence of abscesses of 5% and 100%, respectively.

Target animal safety of Component[®] TE-H is established by data in the FOI Summary for the parent application (ANADA 200-346) approved September 27, 2002. The data provided in the effectiveness study described above were sufficient to conclude that the use of the tylosin pellet was safe for use in cattle. No further studies were required.

3. HUMAN SAFETY

Human safety is established for Component[®] TE-H by data in the FOI Summary in the parent application (ANADA 200-346) which was approved September 27, 2002. No further studies were required for use of the tylosin pellet.

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 trenbolone acetate and estradiol, and tylosin tartrate (Component[®] TE-H with Tylan[®]), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS

Facsimile Generic Labeling is attached as indicated below:

Component[®] TE-H with Tylan[®] Box Label

Component[®] TE-H with Tylan[®] 20 Dose Foil Pouch Label

Component[®] TE-H with Tylan[®] Package Insert