Approval Date: October 22, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-224

COMPONENT T-H and COMPONENT T-S
(Trenbolone Acetate)

COMPONENT T-H with TYLAN and COMPONENT T-S with TYLAN
(Trenbolone Acetate 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 T-H and COMPONENT T-H with TYLAN
Ear Implant for Feedlot Heifers

COMPONENT T-S and COMPONENT T-S with TYLAN
Ear Implant for Feedlot Steers

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-224
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 Trenbolone Acetate with Tylosin
d. Propriety Names:	COMPONENT T-H, COMPONENT T-S, COMPONENT T-H with TYLAN, and COMPONENT T-S with TYLAN
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.2476
f. How Supplied:	COMPONENT T-H: 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. COMPONENT T-H 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 with 29 mg tylosin tartrate as a local antibacterial. COMPONENT T-S: 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 140 mg. COMPONENT T-S 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 140 mg with 29 mg tylosin tartrate as a local antibacterial.
g. How Dispensed:	OTC

h. Amount of Active Ingredients:	COMPONENT T-H: 200 mg trenbolone acetate. COMPONENT T-H with TYLAN: 200 mg trenbolone acetate. 29 mg tylosin tartrate. COMPONENT T-S: 140 mg trenbolone acetate. COMPONENT T-S: 140 mg trenbolone acetate. 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:	Feedlot steers and heifers
k. Recommended Dosage:	COMPONENT T-H: One implant containing 200 mg trenbolone acetate. COMPONENT T-H with TYLAN: One implant containing 200 mg trenbolone acetate with 29 mg tylosin tartrate. COMPONENT T-S: One implant containing 140 mg trenbolone acetate. COMPONENT T-S with TYLAN: One implant containing 140 mg trenbolone acetate with 29 mg tylosin tartrate.
l. Pharmacological Category:	Steroid hormone, anti-bacterial
m. Indications:	COMPONENT T-H and COMPONENT T-H with TYLAN: For increased rate of weight gain and improved feed efficiency. COMPONENT T-S AND COMPONENT T-S with TYLAN: For 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 T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

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 T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

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 T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

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 product 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 T-H with TYLAN and COMPONENT T-S with TYLAN are 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 T-H Carton Label
COMPONENT T-H Foil Pouch (Front)
COMPONENT T-H Foil Pouch (Back)
COMPONENT T-H Package Insert
COMPONENT T-H with TYLAN Carton Label

COMPONENT T-H with TYLAN Foil Pouch (Front)
COMPONENT T-H with TYLAN Foil Pouch (Back)
COMPONENT T-H with TYLAN Package Insert
COMPONENT T-S Carton Label
COMPONENT T-S Foil Pouch (Front)
COMPONENT T-S Foil Pouch (Back)
COMPONENT T-S Package Insert
COMPONENT T-S with TYLAN Carton Label
COMPONENT T-S with TYLAN Foil Pouch (Front)
COMPONENT T-S with TYLAN Foil Pouch (Back)
COMPONENT T-S with TYLAN Package Insert