Approval Date: October 28, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-221

COMPONENT TE-S, COMPONENT TE-IS, and COMPONENT TE-G
(Trenbolone Acetate and Estradiol)

COMPONENT TE-S with TYLAN, COMPONENT TE-IS with TYLAN, and COMPONENT TE-G 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-S, and COMPONENT TE-S with TYLAN
Ear Implants for Steers Fed in Confinement for Slaughter

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

COMPONENT TE-G and COMPONENT TE-G with TYLAN
Ear Implants for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-221
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 Trenbolone Acetate and Estradiol with Tylosin
d. Propriety Names:	COMPONENT TE-S COMPONENT TE-IS COMPONENT TE-G COMPONENT TE-S with TYLAN COMPONENT TE-IS with TYLAN COMPONENT TE-G with TYLAN
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.2477

f. How Supplied:

COMPONENT TE-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 120 mg and estradiol USP 24 mg.

COMPONENT TE-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 120 mg and estradiol USP 24 mg with 29 mg tylosin tartrate as a local antibacterial.

COMPONENT TE-IS: 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 80 mg and estradiol USP 16 mg.

COMPONENT TE-IS 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 80 mg and estradiol USP 16 mg with 29 mg tylosin tartrate as a local antibacterial.

COMPONENT TE-G: 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 40 mg and estradiol USP 8 mg.

COMPONENT TE-G 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 40 mg and estradiol 8 USP mg with 29 mg tylosin tartrate as a local antibacterial.

g. How Dispensed: OTC

h. Amount of Active Ingredients:	COMPONENT TE-S: 120 mg trenbolone acetate. 24 mg estradiol. COMPONENT TE-S with TYLAN: 120 mg trenbolone acetate. 24 mg estradiol. 29 mg tylosin tartrate. COMPONENT TE-IS: 80 mg trenbolone acetate. 16 mg estradiol. COMPONENT TE-IS with TYLAN: 80 mg trenbolone acetate. 16 mg estradiol. 29 mg tylosin tartrate. COMPONENT TE-G: 40 mg trenbolone acetate. 8 mg estradiol. COMPONENT TE-G with TYLAN: 40 mg trenbolone acetate. 8 mg estradiol. 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:	<u>COMPONENT TE-S, COMPONENT TE-S with TYLAN, COMPONENT TE-IS and COMPONENT TE-IS with TYLAN</u>: Steers Fed in Confinement for Slaughter <u>COMPONENT TE-G and COMPONENT TE-G with TYLAN</u>: Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

k. Recommended Dosage:	COMPONENT TE-S: One implant containing 120 mg trenbolone acetate and 24 mg estradiol USP. COMPONENT TE-S with TYLAN: One implant containing 120 mg trenbolone acetate and 24 mg estradiol USP with 29 mg tylosin tartrate. COMPONENT TE-IS: One implant containing 80 mg trenbolone acetate and 16 mg estradiol USP. COMPONENT TE-IS with TYLAN: One implant containing 80 mg trenbolone acetate and 16 mg estradiol USP with 29 mg tylosin tartrate. COMPONENT TE-G: One implant containing 40 mg trenbolone acetate and 8 mg estradiol USP. COMPONENT TE-G with TYLAN: One implant containing 40 mg trenbolone acetate and 8 mg estradiol USP with 29 mg tylosin tartrate.
l. Pharmacological Category:	Steroid hormone, anti-bacterial
m. Indications:	COMPONENT TE-S, COMPONENT TE-S with TYLAN, COMPONENT TE-IS, AND COMPONENT TE-IS with TYLAN: For increased rate of weight gain and improved feed efficiency. COMPONENT TE-G AND COMPONENT TE-G with TYLAN: For increased rate of weight gain.
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-S, COMPONENT

TE-S with TYLAN, COMPONENT TE-IS, COMPONENT TE-IS with TYLAN, COMPONENT TE-G, COMPONENT TE-G with TYLAN (ANADA 200221).

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-S, COMPONENT TE-S with TYLAN, COMPONENT TE-IS, COMPONENT TE-IS with TYLAN, COMPONENT TE-G, COMPONENT TE-G with TYLAN (ANADA 200221).

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-S, COMPONENT TE-S with TYLAN, COMPONENT TE-IS, COMPONENT TE-IS with TYLAN, and COMPONENT TE-G, COMPONENT TE-G with TYLAN (ANADA 200221).

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-S with TYLAN, COMPONENT TE-IS with TYLAN, and COMPONENT TE-G 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 TE-S Carton Label
COMPONENT TE-S Foil Pouch (Front)
COMPONENT TE-S Foil Pouch (Back)
COMPONENT TE-S Package Insert
COMPONENT TE-S with TYLAN Carton Label
COMPONENT TE-S with TYLAN Foil Pouch (Front)
COMPONENT TE-S with TYLAN Foil Pouch (Back)
COMPONENT TE-S with TYLAN Package Insert
COMPONENT TE-IS Carton Label
COMPONENT TE-IS Foil Pouch (Front)
COMPONENT TE-IS Foil Pouch (Back)
COMPONENT TE-IS Package Insert
COMPONENT TE-IS with TYLAN Carton Label
COMPONENT TE-IS with TYLAN Foil Pouch (Front)
COMPONENT TE-IS with TYLAN Foil Pouch (Back)
COMPONENT TE-IS with TYLAN Package Insert
COMPONENT TE-G Carton Label
COMPONENT TE-G Foil Pouch (Front)
COMPONENT TE-G Foil Pouch (Back)
COMPONENT TE-G Package Insert
COMPONENT TE-G with TYLAN Carton Label
COMPONENT TE-G with TYLAN Foil Pouch (Front)
COMPONENT TE-G with TYLAN Foil Pouch (Back)
COMPONENT TE-G with TYLAN Package Insert