Approval Date: April 21, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENT TO AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-346

COMPONENT[â] TE-200 (Trenbolone Acetate and Estradiol)

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

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

Component® TE-200 Ear Implant for Steers 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
d. Propriety Names:	Component® TE-200
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.2477.
f. How Supplied:	As an implant made up of 10 pellets with each pellet containing 20 mg trenbolone acetate and 2 mg estradiol.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Trenbolone acetate: 200 mg trenbolone acetate activity. Estradiol: 20 mg estradiol activity.
i. Route of Administration:	Subcutaneous ear implant
j. Species/Class:	Steers 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 hormone [a natural occurring estrogen, estradiol and a synthetic testosterone, trenbolone acetate].
m. Indications:	For increased rate of weight gain and improved feed efficiency for steers fed in confinement for slaughter.
n. Pioneer Product:	Revalor®-200 (trenbolone acetate and estradiol); NADA 140-992; Intervet, Inc.

o. *Effect of Supplement:* Component® TE-200 for steers is a supplement to the original ANADA 200-346 for Component® TE-H. Component® TE-200 is a higher dose of Component® TE-H, with each pellet in Component® TE-200 (a total of 10 pellets) containing 20 mg trenbolone acetate and 2 mg estradiol in the same formulation as each pellet in Component® TE-H (total of 7 pellets).

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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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, drug 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. The requirements for the *in vivo* blood level bioequivalence study may be waived for certain generic products. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. ANADAs for drug products for food-producing animals will generally be required to include *in vivo* bioequivalence and tissue residue studies. If a waiver of the *in vivo* bioequivalence and/or tissue residue study is granted for a food animal product, then the withdrawal period established for the pioneer product will be assigned to the generic product. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based upon the formulation characteristics of the generic product, Ivy Laboratories, Division of Ivy Animal Health, Inc. was granted a waiver on January 28, 2003, from the requirement of an *in vivo* bioequivalence study for Component® TE-200 (ANADA 200-346). The generic product 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), sponsored by Intervet, Inc. (NADA 140-992), was approved on November 29, 1999.

3. HUMAN SAFETY

- Allowable Incremental Increases and Tolerances for Residues:

  The allowable incremental increases established for the pioneer product apply to the generic product. Estradiol is regulated under 21 CFR 556.240. No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in the uncooked edible tissues of heifers in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 ppt for muscle, 240 ppt for liver, 360 ppt for kidney, and 480 ppt for fat.

The tolerances established for the pioneer product apply to the generic product. Trenbolone acetate is regulated under 21 CFR 556.739. The Acceptable Daily Intake (ADI) for total residues of trenbolone is 0.4 micrograms per kilogram body weight per day. A tolerance for trenbolone residues in uncooked edible tissues of cattle is not needed.

- Withdrawal Time:

  When a generic product demonstrates bioequivalence to the pioneer product in a blood level study where the duration of the study exceeds the withdrawal time assigned to the pioneer product, the generic product is assigned the withdrawal time established for the pioneer product. The zero withdrawal is established for implants containing trenbolone acetate and estradiol.

- Regulatory Method for Residues:

  A regulatory method is not required.

4. AGENCY CONCLUSIONS

This 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 (ANADA 200-346) and currently approved pioneer labeling (NADA 140-992) are attached as indicated below:

Box Label (Generic)
Foil Pouch Label (Generic)
Package Insert (Generic)
Box Label (Pioneer)
Cartridge Label (Pioneer)
Package Insert (Pioneer)

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.