FREEDOM OF INFORMATION SUMMARY
FOR
COMPONENT® TE-G (TRENBOLONE ACETATE AND ESTRADIOL)

1. GENERAL INFORMATION:

ANADA Number: 200-221

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

a. Established Name: Trenbolone Acetate and Estradiol

b. Trade Name: Component® TE-G

c. Dosage Form: Implantation

d. How Supplied: As an implant made up of 2 pellets with each pellet containing 20 mg trenbolone acetate and 4 mg estradiol.

e. How Dispensed: OTC

f. Label Claim of Amount of Active Ingredient(s): 40 mg trenbolone acetate and 8 mg estradiol per implant

g. Route of Administration and Labeled Dosage: Subcutaneous ear implant; one implant containing 40 mg trenbolone acetate and 8 mg estradiol per animal.

h. Species: Cattle

i. Indications for Use: For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).

j. Pioneer Product: Revalor® G; Trenbolone Acetate and Estradiol; NADA 140-897; Hoechst Roussel Vet

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 data and drug effectiveness data are not required for approval of an ANADA. An ANADA relies on the target animal safety and drug effectiveness data in the pioneer's new animal drug application.

Approval of Component® TE-G is granted as a supplement to the original ANADA for Component® TE-S. Component® TE-G is a reduced dose of Component® TE-S with each pellet in Component® TE-G (total of 2 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in Component® TE-S (total of 6 pellets). Likewise, the pioneer product, Revalor® G, is a reduced dose of Revalor® S with each pellet in Revalor® G (total of 2 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in Revalor® S (total of 6 pellets). Component® TE-S has been shown to be bioequivalent to Revalor® S in an adequate and well controlled blood level bioequivalence study in steers fed in confinement for slaughter, which was previously submitted in support of ANADA 200-221. Since Component® TE-S has been shown to be bioequivalent to Revalor® S (each composed of six pellets) in feedlot steers, the release (rate and extent) of TBA and estradiol from the individual pellets in each implant should be bioequivalent to each other in feedlot steers. Likewise, the release (rate and extent) of TBA and estradiol from each pellet (whether from Revalor® G or Component® TE-G) should also be identical in pasture cattle. It is unreasonable to assume that the release (rate and extent) of TBA and estradiol would be different in pasture cattle versus feedlot cattle.

3. HUMAN FOOD SAFETY:

New human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the human food safety data in the pioneer's new animal drug application.

Allowable Incremental Increases and Safe Concentrations of Residues

The allowable incremental increases and safe concentrations established for the pioneer product apply to the generic product. An acceptable daily intake (ADI) of 0.0004 mg/kg body weight/day has been established for trenbolone (64 FR 18573). Estradiol is regulated under 21 CFR 556.240 on the basis of allowable incremental increases. Residues for estradiol and related esters may not exceed the following increments above the concentrations of estradiol naturally present in the untreated animals; in the uncooked edible tissues of heifers, steers, and calves, 120 parts per trillion (ppt) for muscle, 480 ppt in fat, 360 ppt for kidney, and 240 ppt for liver.

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 because the generic product is assigned a zero withdrawal.

4. AGENCY CONCLUSIONS:

The data submitted in support of this ANADA comply with the requirements of section 512 of the Act and demonstrate that Component™ TE-G is safe and effective for the indications stated on the product labeling.

5. LABELING:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

1. Box Label (Generic - Steers)
2. Foil Pouch Label (Generic - Steers)
3. Package Insert (Generic - Steers)
4. Box Label (Generic - Cattle)
5. Foil Pouch Label (Generic - Cattle)
6. Package Insert (Generic - Cattle)
7. Box Label (Pioneer - Steers)
8. Cartridge Label (Pioneer - Steers)
9. Package Insert (Pioneer - Steers)
10. Box Label (Pioneer - Cattle)
11. Cartridge Label (Pioneer - Cattle)
12. Package Insert (Pioneer - Cattle)