

Approval Date: October 28, 2004

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION

ANADA 200-367

SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120
(Trenbolone Acetate and Estradiol)

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:

Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501

FREEDOM OF INFORMATION SUMMARY

SYNOVEX T40 Ear Implant for Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers)

SYNOVEX T80 Ear Implant for Steers Fed in Confinement for Slaughter

SYNOVEX T120 Ear Implant for Steers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-367
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501
Drug Labeler Code: 000856
- c. Established Names: Trenbolone Acetate and Estradiol
- d. Propriety Names: SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2477
- f. How Supplied: SYNOVEX T40: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 2 pellets containing 40 mg trenbolone acetate and 8 mg estradiol.
- SYNOVEX T80: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 4 pellets containing 80 mg trenbolone acetate and 16 mg estradiol.
- SYNOVEX T120: Each box contains 10 pouches each containing 1 cartridge with 10 doses. Each implant dose consists of 6 pellets containing 120 mg trenbolone acetate and 24 mg estradiol.
- g. How Dispensed: OTC

- h. Amount of Active Ingredients: SYNOVEX T40:
40 mg trenbolone acetate.
8 mg estradiol.
- SYNOVEX T80:
80 mg trenbolone acetate.
16 mg estradiol.
- SYNOVEX T120:
120 mg trenbolone acetate.
24 mg estradiol.
- 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: SYNOVEX T40: Pasture Cattle (Slaughter, Stocker, and Feeder Steers and Heifers).
- SYNOVEX T80 and SYNOVEX T120: Steers Fed in Confinement for Slaughter.
- k. Recommended Dosage: SYNOVEX T40: One implant containing 40 mg trenbolone acetate and 8 mg estradiol.
- SYNOVEX T80: One implant containing 80 mg trenbolone acetate and 16 mg estradiol.
- SYNOVEX T120: One implant containing 120 mg trenbolone acetate and 24 mg estradiol.
- l. Pharmacological Category: Steroid hormones
- m. Indications: SYNOVEX T40: Increases rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers) in a slow-release delivery system.
- SYNOVEX T80 and SYNOVEX T120: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

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 SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

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 SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

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 SYNOVEX T40, SYNOVEX T80, and SYNOVEX T120 (ANADA 200367).

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.

No patent information was submitted with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

SYNOVEX T40 Carton Label
SYNOVEX T40 Pouch (Front and Back)
SYNOVEX T80 Carton Label
SYNOVEX T80 Pouch (Front and Back)
SYNOVEX T120 Carton Label
SYNOVEX T120 Pouch (Front and Back)