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Application No.	5/8/00
Application Date	5/9/00
Certifier	[Signature]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 522**

**Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental ANADA provides for subcutaneous use of a cattle ear implant containing trenbolone and estradiol for pasture cattle for increased rate of weight gain. Technical changes are also made.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217.

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200-221 for use of Component® TE-G (40 milligrams (mg) trenbolone acetate and 8 mg estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol) for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers). The supplemental ANADA is approved as of March 6, 2000, and the regulations in 21 CFR 522.2477 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support cv9976

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approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 522**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### **PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 522.2477 is amended by revising paragraphs (b), (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3)(i) to read as follows:

#### **§ 522.2477     Trenbolone acetate and estradiol.**

\*   \*   \*   \*   \*

(b) *Sponsors.* See No. 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See No. 021641

in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), (d)(1)(iii), and (d)(3) of this section.

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(d) \* \* \*

(1) \* \* \*

(i) \* \* \*

(A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

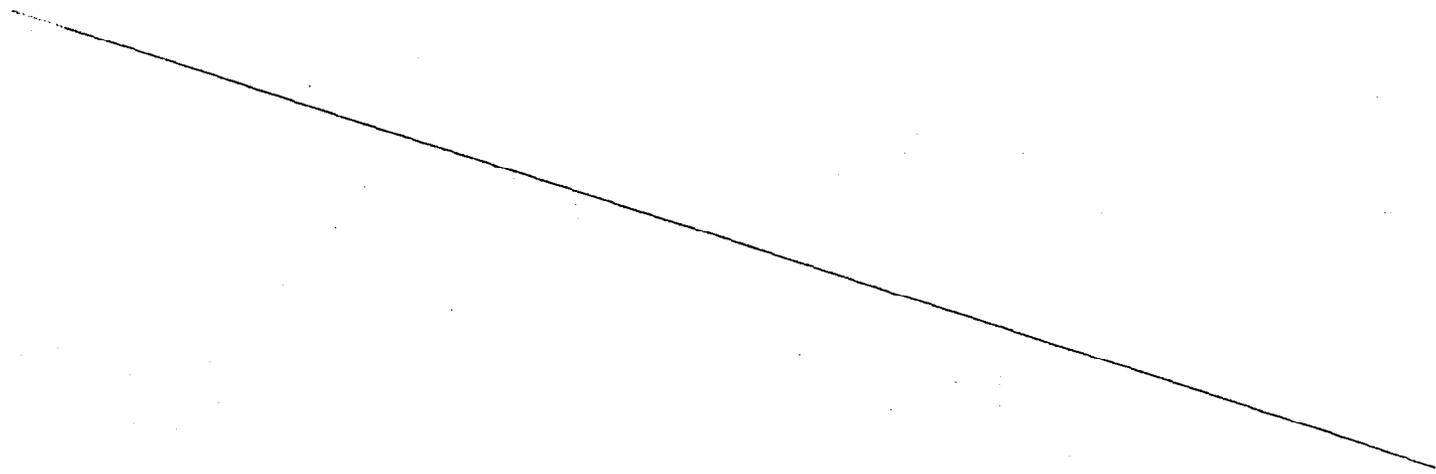
(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

\* \* \* \* \*

(2) *Heifers fed in confinement for slaughter*—(i) *Amount.* 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

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(3) \* \* \* (i) Amount. 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

\* \* \* \* \*

Dated: 4/25/00

April 25, 2000

Claire M. Lathers

Claire M. Lathers  
Director  
Office of New Animal Drug  
Evaluation  
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

*Jan Windsor*

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