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Certifier	J. Caldwell

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 522**

**Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate 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 new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for use of a higher dose ear implant containing trenbolone acetate and estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

**EFFECTIVE DATE:** *[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:** Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 140-992 that provides for use of Revalor®-200, an ear implant containing 200 milligrams (mg) of trenbolone acetate and 20 mg of estradiol in 10 pellets. The implant is used for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of November 29, 1999, and the regulations are amended in 21 CFR 522.2477 by revising paragraph (b), the heading in paragraph (d)(1), and by adding paragraph (d)(1)(i)(C) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

cv9971 NADA 140-992

NFR-1

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 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on November 29, 1999, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the ear implant containing 200 mg trenbolone acetate and 20 mg estradiol for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

FDA 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 paragraph (b), by removing in paragraph (d)(1) the heading “Feedlot steers” and by adding in its place “Steers fed in confinement for slaughter”, and by adding paragraph (d)(1)(i)(C) to read as follows:

**§ 522.2477    Trenbolone acetate and estradiol.**

\*   \*   \*   \*   \*

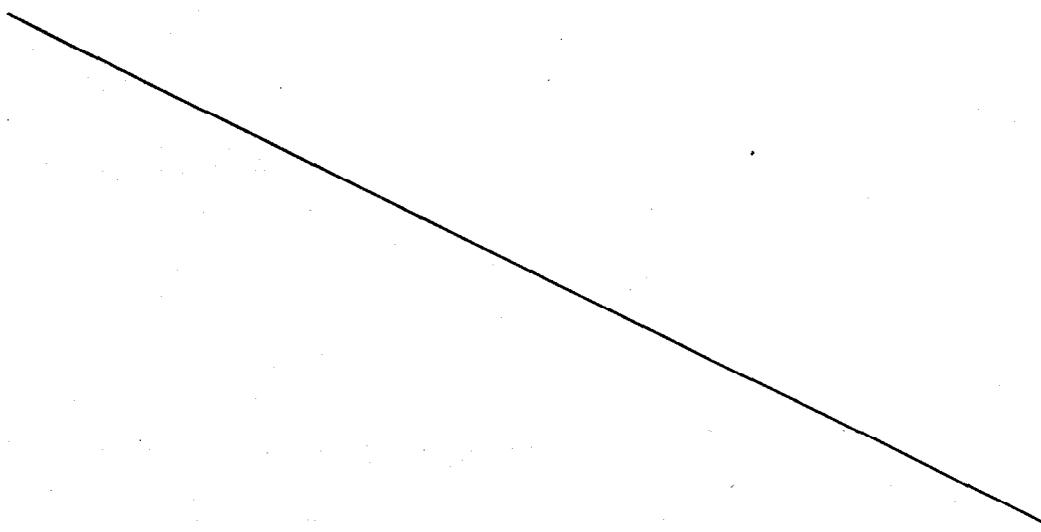
(b) *Sponsors.* See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), and (d)(1)(iii) of this section.

\*   \*   \*   \*   \*

(d) \* \* \*

(1) \* \* \*

(i) \* \* \*



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

\* \* \* \* \*

Dated: 1/28/2000  
January 28, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

*Jen Windsor*

*Claire M. Lathers*

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

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