

## 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; Technical Amendment

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

**ACTION:** Final rule; technical amendment.

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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, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot steers for increased rate of weight gain and improved feed efficiency. This section of the regulations is also being amended to remove a redundant description of another strength implant. This action is being taken to improve the accuracy of the regulations.

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

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: [edubbin@cvm.fda.gov](mailto:edubbin@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200-221 for COMPONENT TE-IS (trenbolone acetate/estradiol), a subcutaneous ear implant containing 80 milligrams (mg) trenbolone acetate

and 16 mg estradiol, in four pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol. The implants are used in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE-IS is approved as a generic copy of Intervet, Inc.'s REVALOR-IS, approved under NADA 140-897. The supplemental application is approved as of September 3, 2003, and 21 CFR 522.2477 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.2477 is being amended to remove a redundant description of another strength implant. This action is being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (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 in paragraph (b)(1) by removing “(d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(ii)” and by adding in its place “(d)(1)”; and by revising paragraph (d)(1)(i)(D) to read as follows:

**§ 522.2477     Trenbolone acetate and estradiol.**

\*     \*     \*     \*     \*

(d) \* \* \*

(1) \* \* \*

(i) \* \* \*

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

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Dated: September 15, 2003.

**Steven D. Vaugh,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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