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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier D. Hawkins

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for subcutaneous use of an implant containing trenbolone acetate and estradiol for increased rate of weight gain and improved feed efficiency in feedlot heifers.

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

FOR FURTHER INFORMATION CONTACT: Harlan J. Howard, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0231, hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200-346 for COMPONENT TE-H (140 milligrams (mg) trenbolone acetate and 14 mg estradiol, in seven pellets, each pellet containing 20 mg of trenbolone acetate and 2 mg of estradiol) for increased rate of weight gain and improved feed efficiency in heifers fed in confinement for slaughter. Ivy Laboratories' COMPONENT TE-H is approved as a generic copy of Intervet's REVALOR-

H, approved under NADA 140-992. The application is approved as of September 27, 2002, and the regulations are amended in 21 CFR 522.2477 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 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:

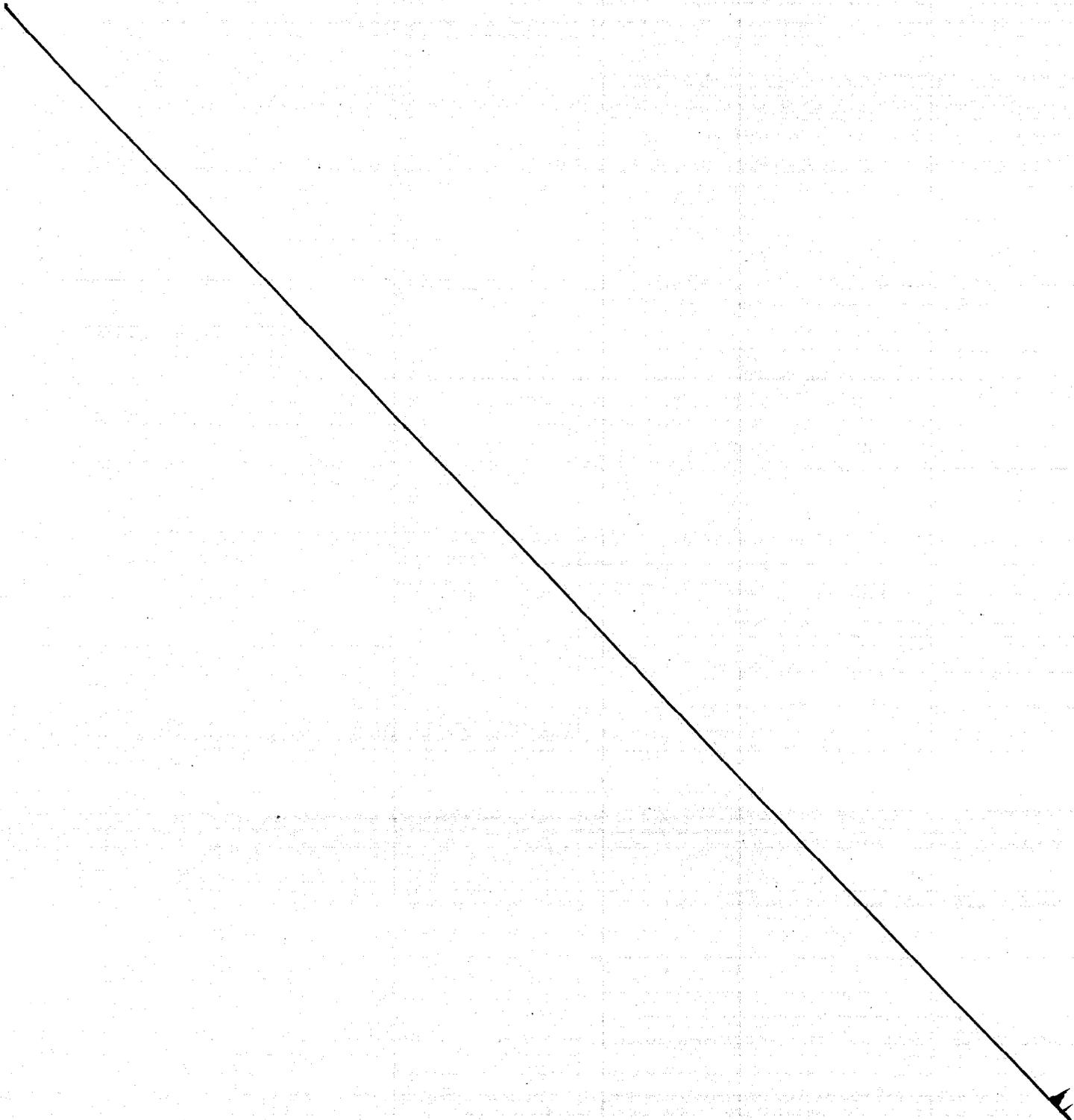
PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.2477 [Amended]

2. Section 522.2477 *Trenbolone acetate and estradiol* is amended in paragraph (b)(1) by adding “(d)(2)(i)(A), (d)(2)(ii)(A), (d)(2)(iii),” after “(d)(1)(iii),”.



Dated: 12/17/02
December 17, 2002.

SF Sundlof

Stephen F. Sundlof
Director,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Dawn P. Hawkins