

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 522

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 a supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Inc. The supplemental ANADA provides for adding tylosin tartrate as a local antibacterial to an approved subcutaneous cattle ear implant containing trenbolone and estradiol used in pasture cattle for increased rate of weight gain.

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

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200-221 for COMPONENT® TE-G (trenbolone acetate/estradiol) with Tylan®, a subcutaneous ear implant containing 40 of milligrams (mg) trenbolone acetate and 8 mg of estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol, and an additional pellet containing 29 mg of tylosin tartrate as a local antibacterial. The implants are used in pasture cattle (slaughter, stocker, and feeder steers and heifers) for increased rate of weight gain. The supplemental application is approved as of September 18, 2000, 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.

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 September 18, 2000, because the 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 the addition of tylosin tartrate to the implant for which the supplemental application was approved.

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 the first sentence of paragraph (b) by removing “(d)(3)” and by adding in its place “(d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii)” ; in the second sentence of paragraph (b) by removing “(d)(3)” and by adding in its place “(d)(3)(i)(A), (d)(3)(i)(B), (d)(3)(ii), and (d)(3)(iii)” ; and by revising paragraph (d)(3)(i) to read as follows:

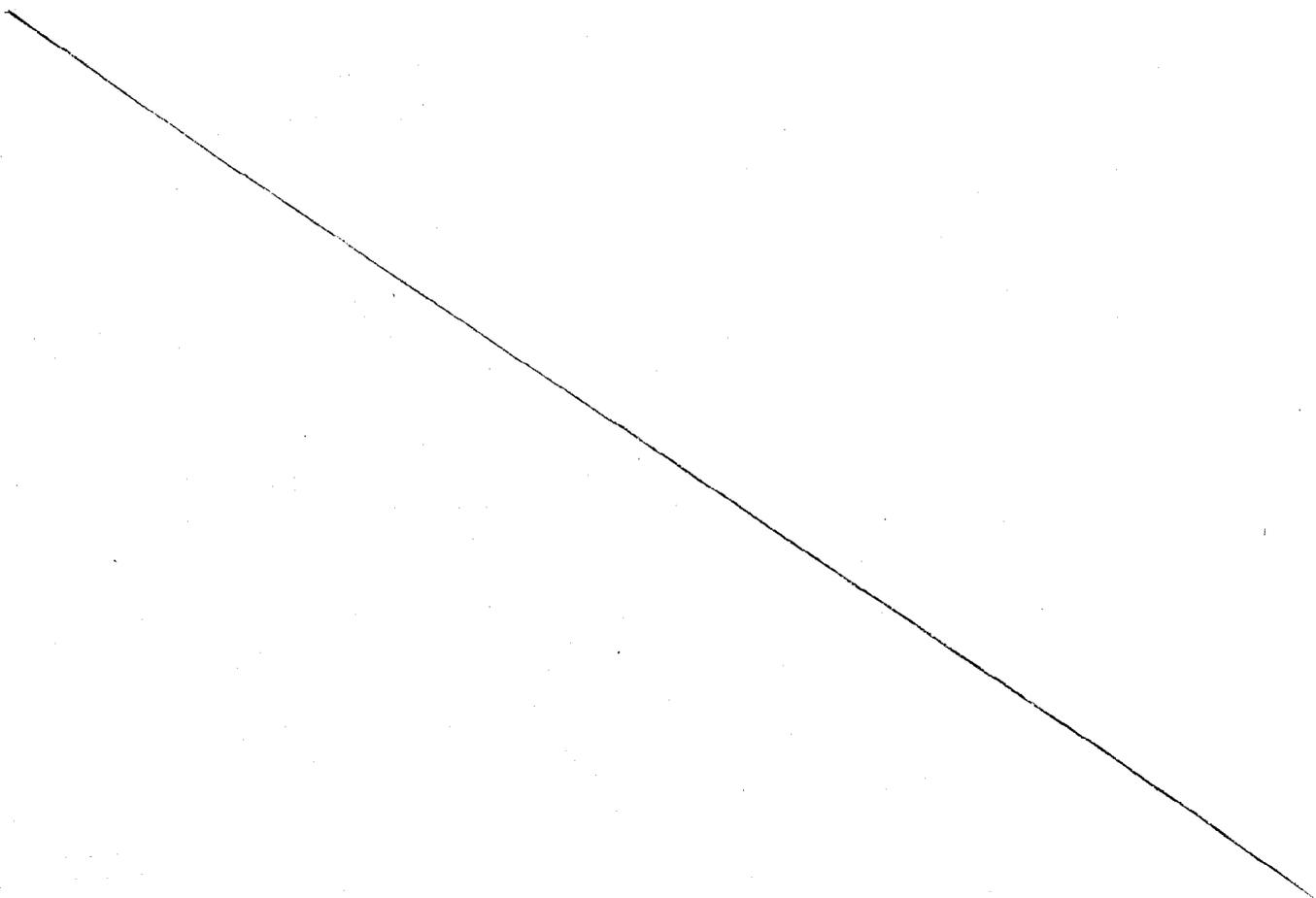
§ 522.2477 Trenbolone acetate and estradiol.

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(d) * * *

(3) * * *

(i) *Amount.* (A) 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.



(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

* * * * *

Dated: 10/11/00
October 11, 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**

[Signature]

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