

Members is the six member Executive Committee. The Executive Committee is comprised of the General Counsel, who also serves as the Senior Executive Officer, the Director of Administration, the Director of Programs, the Chief Financial Officer, the Chief Information Officer, and the Chief Actuary.

(2) The Executive Committee is responsible for the day to day operations of the agency. The Senior Executive Officer is responsible for direction and oversight of the Executive Committee. The General Counsel is responsible for advising the Board Members on major issues, interpreting the Acts and regulations administered by the Board, drafting and analyzing legislation, and planning, directing, and coordinating the work of the Office of General Counsel, the Bureau of Hearings and Appeals, and the Office of Legislative Affairs through their respective directors, and the Office of Secretary to the Board. The Director of Programs is responsible for managing, coordinating, and controlling the program operations of the agency which carry out provisions of the Railroad Retirement and Railroad Unemployment Insurance Acts. The Director of Administration is responsible for managing, coordinating, and controlling certain administrative operations of the Board including the Bureau of Supply and Service, the Bureau of Human Resources, the Office of Public Affairs, and the Office of Equal Opportunity. The Chief Financial Officer is responsible for the financial management of the agency, and the Chief Information Officer is responsible for coordinating the agency's information resources management program. The Board's Chief Actuary is responsible for the actuarial program of the Board. The Chief Actuary is a non-voting member of the Executive Committee.

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Dated: February 1, 2002.

By Authority of the Board, for the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 02-2943 Filed 2-6-02; 8:45 am]

BILLING CODE 7905-01-P

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.

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 Intervet, Inc. The supplemental NADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective February 7, 2002.

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, e-mail: dbenz@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed supplemental NADA 140-992 that provides for REVALOR-200 ear implants containing 200 milligrams (mg) trenbolone acetate and 20 mg estradiol for heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of December 6, 2001, 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 (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning

December 6, 2001, because the application contains substantial evidence of the effectiveness of the drugs 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 approval of the application and conducted or sponsored by the applicant.

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 the 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 adding paragraph (d)(2)(i)(C) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(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 for use as in paragraph (d)(2)(ii)(A) of this section.

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Dated: January 11, 2002.

Claire M. Lathers,

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

[FR Doc. 02-2949 Filed 2-6-01; 8:45 am]

BILLING CODE 4160-01-S