

Substances	Limitations
<p style="text-align: center;">* * * * *</p> <p>2-[4,6-Bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol (CAS Reg. No. 2725-22-6).</p> <p style="text-align: center;">* * * * *</p>	<p>For use only:</p> <ol style="list-style-type: none"> <li>1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter in contact with food types I, II, IV-B, VI, VII-B, and VIII described in § 176.170(c) of this chapter, table 1, under conditions of use D through G as described in § 176.170(c), table 2, of this chapter.</li> <li>2. At levels not to exceed 0.1 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1a, 1.2, and 1.3 in contact with food under conditions of use A through H as described in § 176.170(c), table 2, of this chapter.</li> <li>3. At levels not to exceed 0.04 percent by weight of polyethylene and olefin copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b having a minimum density of 0.94 gram per cubic centimeter, in contact with food under conditions of use A through H as described in § 176.170, table 2, of this chapter provided that the finished articles used in contact with fatty food types III, IV-A, V, VII-A, and IX as described in table 1 of § 176.170(c) of this chapter hold a minimum of 2 gallons (7.6 liters) of food.</li> <li>4. At levels not to exceed 0.4 percent by weight of ethylene copolymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b, having a density of less than 0.94 gram per cubic centimeter, in contact with food under conditions of use B through H, as described in § 176.170(c), table 2, of this chapter provided that the finished articles used in contact with fatty food types III, IV-A, V, VII-A, and IX hold a minimum of 5 gallons (18.9 liters) of food.</li> <li>5. At levels not to exceed 0.04 percent by weight of polyethylene having a density of less than 0.94 gram per cubic centimeter, and olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.3a, 3.3b, 3.4, 3.5, 3.6, 4, 5, and 6, in contact with food under conditions of use D through G as described in § 176.170(c) of this chapter, table 2, provided that the finished articles used in contact with fatty food types III, IV-A, V, VII-A, and IX hold a minimum of 5 gallons (18.9 liters) of food.</li> </ol> <p style="text-align: center;">* * * * *</p>

Dated: April 27, 2000

**L. Robert Lake,**

*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

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## 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 abbreviated new animal drug application (ANADA)

filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental ANADA provides for subcutaneous use of a cattle ear implant containing trenbolone and estradiol for pasture cattle for increased rate of weight gain. Technical changes are also made.

**DATES:** This rule is effective May 9, 2000.

**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:** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200-221 for use of Component® TE-G (40 milligrams (mg) trenbolone acetate and 8 mg estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol) for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers). The supplemental ANADA is

approved as of March 6, 2000, and the regulations in 21 CFR 522.2477 are amended 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.

2. Section 522.2477 is amended by revising paragraphs (b), (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3)(i) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

\* \* \* \* \*

(b) Sponsors. See No. 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 No. 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), (d)(1)(iii), and (d)(3) of this section.

\* \* \* \* \*

- (d) \* \* \*
(1) \* \* \*
(i) \* \* \*

(A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(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.

(ii) Indications for use. For increased rate of weight gain and improved feed efficiency.

\* \* \* \* \*

(2) Heifers fed in confinement for slaughter—(i) Amount. 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone

acetate and 2 mg estradiol) per implant dose.

(ii) Indications for use. For increased rate of weight gain and improved feed efficiency.

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(3) \* \* \* (i) Amount. 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.

\* \* \* \* \*

Dated: April 25, 2000.

Claire M. Lathers,

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

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 727

RIN 0703-AA59

Legal Assistance

AGENCY: Department of the Navy, DOD. ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its regulations concerning the provision of legal assistance to military members and other persons eligible for legal assistance to reflect recent changes to Chapter VII of the Manual of the Judge Advocate General.

DATES: Effective May 9, 2000.

ADDRESSES: Office of the Judge Advocate General (Code 36), 1322 Patterson Avenue SE, Suite 3000, Washington Navy Yard, DC 20374-5066.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Steven L. Haycock, Judge Advocate General's Corps, U.S. Navy, Office of the Judge Advocate General (Code 36), 1322 Patterson Avenue SE, Suite 3000, Washington Navy Yard, DC 20374-5066, Telephone number (202) 685-4642.

SUPPLEMENTARY INFORMATION: Pursuant to the authority cited below, the Department of the Navy amends 32 CFR Part 727, which is derived from Chapter VII of the Manual of the Judge Advocate General, to reflect changes to that regulation. The amendment relates to internal naval management and personnel practices, and is being published by the Department of the Navy solely for the guidance and interest of the public in accordance with 5 U.S.C. 552(a)(1). It has been

determined that invitation of public comment on this amendment prior to adoption would be impracticable and is not required under the public rulemaking provisions of 32 CFR parts 296 and 701. It has also been determined that this rule is not a "significant regulatory action" as defined in Executive Order 12866.

List of Subjects in 32 CFR Part 727

Legal services, Military law, Military personnel.

Accordingly, 32 CFR part 727 is amended as follows:

PART 727—LEGAL ASSISTANCE

1. The authority citation for part 727 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 5031 and 5148; 32 CFR 700.206 and 700.1202.

2. Revise § 727.5 to read as follows:

§ 727.5 Persons eligible for assistance.

Legal assistance shall be available to members of the Armed Forces of the United States and their dependents, and military personnel of allied nations serving in the United States, its territories or possessions. Legal assistance is intended primarily for the benefit of active duty personnel during active service, including reservists (and members of the National Guard) on active duty for 30 days or more. As resources permit, legal assistance may be extended to retired military personnel, their dependents, survivors of members of the Armed Forces who would be eligible were the service member alive, reservists on active duty for single periods of 29 days or less, and in overseas areas, to civilians, other than local-hire employees, who are in the employ of, serving with, or accompanying the U.S. Armed Forces, and their dependents, when and if the workload of the office renders such service feasible, and other persons authorized by the Judge Advocate General of the Navy.

3. Amend § 727.6 by revising paragraphs (a) introductory text, (a)(2), (a)(6), and (d) to read as follows:

§ 727.6 Functions of legal assistance officers.

(a) Basic duties. A legal assistance officer, while performing legal assistance duties, in addition to performing any other duties which may be assigned to him/her:

\* \* \* \* \*

(2) Shall serve as advocate and counsel for persons eligible for assistance in connection with their personal legal problems and may