

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs; Estradiol Benzoate and Testosterone Propionate

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth, and Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing estradiol benzoate and testosterone propionate warning against the use of these products in calves to be processed for veal.

**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:** Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 011-427 for SYNOVEX H (estradiol benzoate and testosterone propionate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 135-906 for COMPONENT E-H (estradiol benzoate and testosterone propionate) and COMPONENT E-H

with TYLAN (estradiol benzoate and testosterone propionate with tylosin tartrate). The supplemental NADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 18, 2004, and the regulations are amended in 21 CFR 522.842 to reflect the approvals and a current format. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 these actions are of a type that do 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 522.842 is revised to read as follows:

### **§ 522.842 Estradiol benzoate and testosterone propionate.**

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 000856 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.

(2) No. 021641 for use as in paragraph (c) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(c) *Conditions of use.* For implantation in heifers as follows:

(1) *Amount.* (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

(ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

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

(3) *Limitations.* For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established

in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 5, 2004.

**Steven D. Vaughn,**

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

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