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Certifier	Jan Winder

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 522 and 556**

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

**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 Fort Dodge Animal Health. The supplemental NADA provides for use of a trenbolone acetate-estradiol benzoate implant in steers fed in confinement for slaughter for increased rate of weight gain. At this time, FDA is also amending the regulation for trenbolone tolerances to establish an acceptable daily intake (ADI) for the drug.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center For Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-0217.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141-043 that provides for use of Synovex® Plus™ (200 milligrams (mg) trenbolone acetate and 28 mg estradiol benzoate) implanted in the ear of steers fed in confinement for slaughter for increased rate of weight gain in addition to its approved use for improved feed efficiency. The supplemental NADA is approved as of March 16, 1999. The regulations are amended in 21 CFR 522.2478 by redesignating paragraph 3

(c) as (d), adding paragraph (c), and revising newly redesignated paragraph (d)(1)(ii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, an ADI for trenbolone has not been previously established. At this time, 21 CFR 556.739 is amended to provide an ADI for trenbolone.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.110, 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 21 U.S.C. 360b(c)(2)(F)(iii), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 16, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, 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 and conducted or sponsored by the applicant. Market exclusivity applies only to use of the implant for increased rate of weight gain in confined steers.

FDA has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

## **List of Subjects**

### **21 CFR Part 522**

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are 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 522.2478 is amended by redesignating paragraph (c) as (d), reserving paragraph (c), and revising paragraph (d)(1)(ii) to read as follows:

**§ 522.2478**      **Trenbolone acetate and estradiol benzoate.**

\*      \*      \*      \*      \*

(c) [Reserved]

(d) \* \* \*

(1) \* \* \*

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

\*      \*      \*      \*      \*

**PART 556-TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

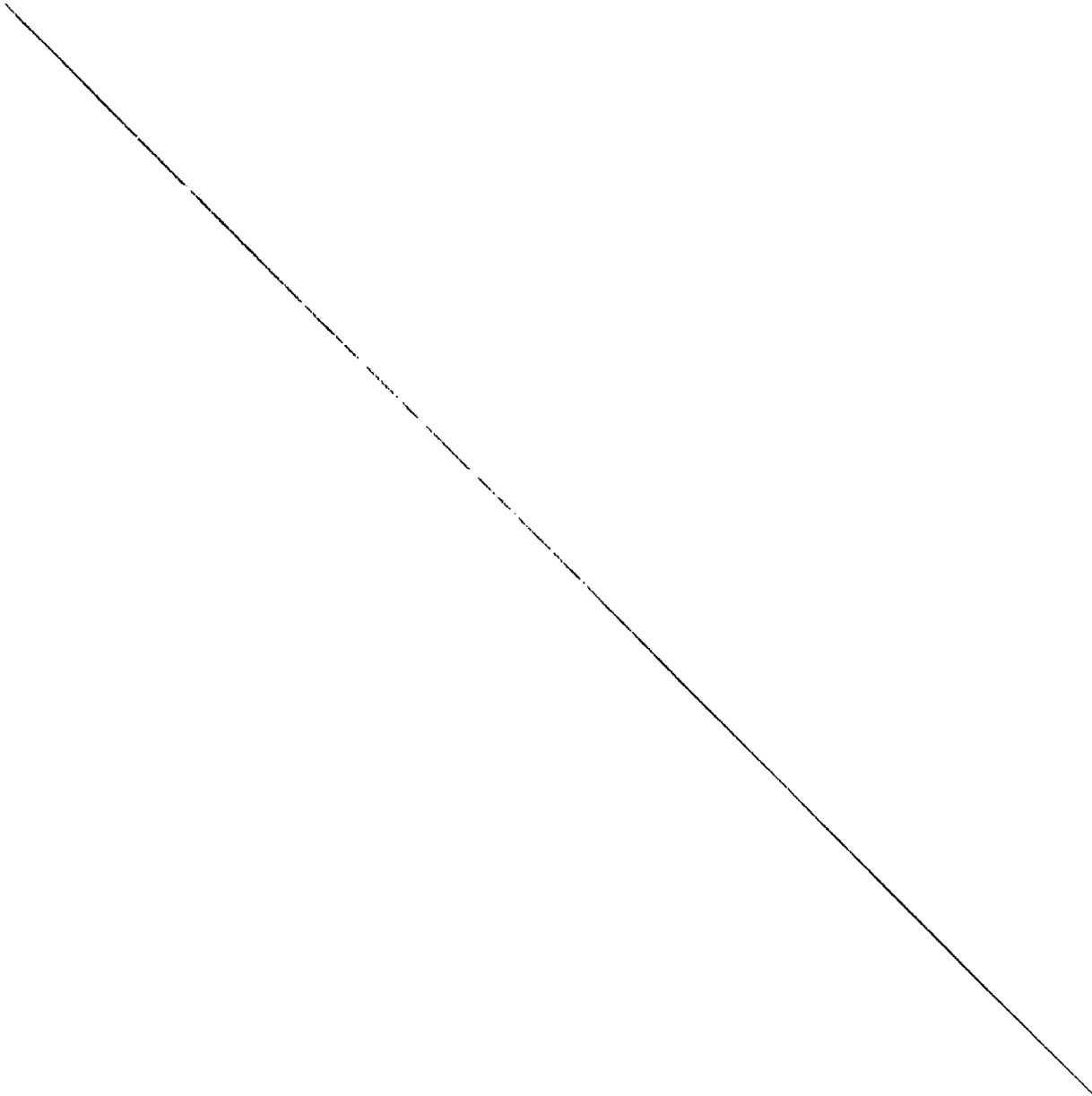
3. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

4. Section 556.739 is revised to read as follows:

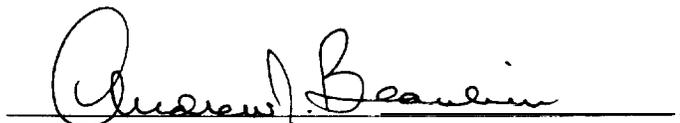
**§ 556.739 Trenbolone.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of trenbolone is 0.4 microgram per kilogram of body weight per day.



(b) *Tolerances*. A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed.

Dated: April 1, 1999



Andrew J. BeauLieu  
Deputy Director  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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