

editorial in nature, and is intended to provide accuracy and clarity to the agency's regulations.

DATES: Effective April 1, 1996.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 172, 173, 175, 176, 177, 178, 180, 181, and 189 to reflect a change in the name and address for the Association of Official Analytical Chemists International. The current name and address listed in FDA's regulations is Association of Official Analytical Chemists, 2300 Wilson Blvd., Suite 400, Arlington, VA 22201-3301. The new name and address is Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504.

To reflect an organizational change within CFSAN, FDA is amending the regulations to remove references to the Division of Food and Color Additives.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are editorial and nonsubstantive in nature.

List of Subjects

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Parts 173 and 180

Food additives.

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Parts 176, 177, and 178

Food additives, Food packaging.

21 CFR Parts 181 and 189

Food ingredients, Food packaging.

Therefore under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 172, 173, 175, 176, 177, 178, 180, 181, and 189 are amended as follows:

1. In parts 172, 173, 176, 177, 178, and 189 remove the words "Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301" and add in its place the words "Association of Official Analytical Chemists International, 481

North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504" wherever it appears.

2. In parts 172, 173, 175, 176, 177, 178, 180, and 181 remove the phrase "Division of Food and Color Additives," and remove the mail code "(HFF-330)" and add in its place "(HFS-200)" wherever it appears.

Dated: March 26, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-7919 Filed 4-1-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

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 new animal drug application (NADA) filed by Syntex Animal Health. The NADA provides for use of an ear implant containing trenbolone acetate and estradiol benzoate in steers fed in confinement for slaughter for improved feed efficiency.

EFFECTIVE DATE: April 2, 1996.

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: Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, filed NADA 141-043, which provides for use of an ear implant consisting of 8 pellets, each pellet containing 25 milligrams (mg) of trenbolone acetate and 3.5 mg of estradiol benzoate. The implant is used in steers fed in confinement for slaughter for improved feed efficiency. The NADA is approved as of February 22, 1996, and the regulations are amended by adding new 21 CFR 522.2478 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for a 3-year period of marketing exclusivity beginning on February 22, 1996, because new clinical or field investigations (other than bioequivalence or residue studies), or human food safety studies (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant.

The agency 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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.2478 is added to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Sponsor.* See 000033 in § 510.600(c) of this chapter.

(b) *Related tolerance.* See §§ 556.240 and 556.739 of this chapter.

(c) *Conditions of use—(1) Steers—(i) Amount.* 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.

(ii) *Indications for use.* For improved feed efficiency in steers fed in confinement for slaughter.

(iii) *Limitations*. Implant subcutaneously in ear only.
(2) [Reserved]

Dated: March 14, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-7901 Filed 4-1-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazine, Roxarsone, and Lincomycin; Nicarbazine and Lincomycin; Nicarbazine and Roxarsone

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 three abbreviated new animal drug applications (ANADA's) filed by Planalquimica Industrial Ltda. The ANADA's provide for use of single ingredient nicarbazine, roxarsone, and lincomycin Type A medicated articles to make combination drug Type C medicated broiler feeds containing nicarbazine, roxarsone, and lincomycin; nicarbazine and lincomycin; or nicarbazine and roxarsone.

EFFECTIVE DATE: April 2, 1996.

FOR FURTHER INFORMATION CONTACT:

James F. McCormack, Center For Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1607.

SUPPLEMENTARY INFORMATION:

Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil, filed the following ANADA's:

ANADA 200-170: Nicarbazine with roxarsone and lincomycin, for Type C medicated feeds, as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis; for increased rate of weight gain, in broiler chickens;

ANADA 200-171: Nicarbazine and lincomycin, for Type C medicated feeds, as an aid in preventing outbreaks of cecal (*E. tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis; for increased rate of weight gain, in broiler chickens;

ANADA 200-172: Nicarbazine and roxarsone, for Type C medicated feeds, as an aid in preventing outbreaks of cecal (*E. tenella*) and intestinal (*E.*

acervulina, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis; for increased rate of weight gain, in broiler chickens.

The ANADA's provide for use of previously approved single ingredient Type A medicated articles to make combination drug Type C medicated feeds. Planalquimica's ANADA 200-170 is approved as a generic copy of Merck Research Laboratories' NADA 107-997, ANADA 200-171 as a generic copy of Merck's NADA 108-116, and ANADA 200-172 as a generic copy of Merck's 108-115. The ANADA's are approved as of April 2, 1996, and the regulations are amended in 21 CFR 558.366(c) to reflect the approvals. The basis for approval is discussed in the freedom of information summary.

These approvals are for use of Type A medicated articles to make Type C medicated feeds. Nicarbazine and roxarsone are Category II drugs which, as provided in 21 CFR 558.4, require an approved Form FDA 1900 for making a Type C medicated feed. Therefore, use of nicarbazine to make combination drug Type C medicated feeds as provided in ANADA 200-170, 200-171, and 200-172 require an approved Form FDA 1900.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.366 [Amended]

2. Section 558.366 *Nicarbazine* is amended in the table in paragraph (c) under the "Sponsor" column for the entries "Lincomycin 2 (0.00044 pct)," "Roxarsone 22.7 (0.0025)," and "Roxarsone 22.7 (0.0025) plus lincomycin 2 (0.0004)" by removing "000006" and adding in its place "000006, 060728".

Dated: March 19, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-7977 Filed 4-1-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF EDUCATION

34 CFR Part 76 and 81

RIN 1880-AA64

State-Administered Programs; General Education Provisions Act—Enforcement

AGENCY: Department of Education.

ACTION: Final Regulations; Correction.

SUMMARY: On September 6, 1995, the Secretary of Education published in the Federal Register (60 FR 46492) final regulations which made technical amendments to the Education Department General Administrative Regulations (EDGAR) to implement amendments to the General Education Provisions Act (GEPA) made by the Improving America's Schools Act (IASA). This document corrects authority cites under Part 76, State-Administered Programs and Part 81, General Education Provisions Act—Enforcement.

EFFECTIVE DATE: This correction is effective October 6, 1995.

FOR FURTHER INFORMATION CONTACT:

Ronelle Holloman, U.S. Department of Education, 600 Independence Avenue, S.W., Room 3636, ROB-3, Washington, D.C. 20202-4248. Telephone: (202) 205-3501. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The final regulations published on September 6 stated authority citations for §§ 76.703 and 76.704 incorrectly, included an authority citation for § 76.705, which was previously redesignated, and failed to include authority citations for §§ 76.708, 76.709 and 76.710. Sections of Part 81 were also previously redesignated on August 16, 1993 (58 FR