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*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200–221 for COMPONENT TE–IS (trenbolone acetate/estradiol), a subcutaneous ear implant containing 80 milligrams (mg) trenbolone acetate and 16 mg estradiol, in four pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol. The implants are used in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE–IS is approved as a generic copy of Intervet, Inc.'s REVALOR–IS, approved under NADA 140–897. The supplemental application is approved as of September 3, 2003, and 21 CFR 522.2477 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.2477 is being amended to remove a redundant description of another strength implant. This action is being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 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 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 in paragraph (b)(1) by removing ''(d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(ii)'' and by adding in its place ''(d)(1)''; and by revising paragraph (d)(1)(i)(D) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

* * * * *

Dated: September 15, 2003.

Steven D. Vaugh,

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

[FR Doc. 03–24161 Filed 9–22–03; 8:45 am]

BILLING CODE 4160–01–S

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, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain.

DATES: This rule is effective September 23, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200–346. The supplemental ANADA provides for the use of COMPONENT TE–IH (trenbolone acetate and estradiol), a subcutaneous implant containing 80 milligrams (mg) trenbolone acetate and 8 mg estradiol in heifers fed in confinement for slaughter for increased rate of weight gain. Ivy Laboratories' COMPONENT TE–IH is approved as a generic copy of Intervet, Inc.'s REVALOR–IH, approved under NADA 140–992. The application is approved as of August 19, 2003, 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 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 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 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.

§ 522.2477 [Amended]

■ 2. Section 522.2477 *Trenbolone acetate and estradiol* is amended in paragraph (b)(1) by removing ''(d)(2)(ii)(A),'' and by adding in its place ''(d)(2)(i)(C),''.

Dated: September 15, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–24157 Filed 9–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Nystatin, Neomycin, Thiostrepton, and Triamcinolone Acetonide Ointment

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 an abbreviated new animal drug application (ANADA) filed by Altana, Inc. The ANADA provides for topical dermatologic use in dogs and cats of a nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment in a vanishing cream base.

DATES: This rule is effective September 23, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Altana, Inc., 60 Baylis Rd., Melville, NY 11747, filed ANADA 200–330 that provides for use of ANIMAX (nystatin, neomycin, thiostrepton, and triamcinolone acetonide) Cream Veterinary, a vanishing cream based ointment, for topical dermatologic use in dogs and cats. Altana, Inc.'s ANIMAX Cream Veterinary is approved as a generic copy of Fort Dodge Animal Health's PANOLOG Cream, approved under NADA 96–676. The ANADA is approved as of September 4, 2003, and the regulations in 21 CFR 524.1600a 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 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 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 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 524

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 524 is amended as follows:

OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1600a [Amended]

■ 2. Section 524.1600a *Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment* is amended in paragraph (b) in the second sentence by removing ''051259 and 053501'' and by adding in its place ''Nos. 025463, 051259, and 053501''.

Dated: September 15, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–24160 Filed 9–22–03; 8:45 am]

BILLING CODE 4160–01–S