§ 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