

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2008-N-0039]

### 21 CFR Part 524

## Ophthalmic and Topical Dosage Form New Animal Drugs; Triamcinolone Cream

**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 an abbreviated new animal drug application (ANADA) filed by Modern Veterinary Therapeutics, LLC. The ANADA provides for veterinary prescription use of triamcinolone cream on dogs for topical treatment of allergic dermatitis and summer eczema.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146, filed ANADA 200-459 that provides for veterinary prescription use of VETAZINE (triamcinolone acetate) Cream on dogs for topical treatment of allergic dermatitis and summer eczema. Modern Veterinary Therapeutics, LLC's VETAZINE Cream is approved as a generic copy of VETALOG Cream, sponsored by Fort Dodge

Animal Health, A Division of Wyeth Holdings Corp., under NADA 46–146. The ANADA is approved as of November 13, 2008, and the regulations are amended in § 524.2481 to reflect the approval.

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 524 is amended as follows:

### **PART 524—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.

■ 2. In § 524.2481, revise paragraphs (b), (c)(2), and (c)(3) to read as follows:

**§ 524.2481 Triamcinolone cream.**

\* \* \* \* \*

(b) *Sponsor.* See Nos. 015914, 053501, and 054925 in § 510.600(c) of this chapter.

(c) \* \* \*

(2) *Indications for use.* For topical treatment of allergic dermatitis and summer eczema.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 18, 2008.

**William T. Flynn,**

*Acting Director, Center for Veterinary Medicine.*

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