

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

JMB

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**Ophthalmic and Topical Dosage Form New Animal Drugs; Chloramphenicol, etc.;
Withdrawal of Approval of NADAs**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions that reflect approval of two new animal drug applications (NADAs) held by EVSCO Pharmaceuticals, an Affiliate of IGI, Inc. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

DATES: This rule is effective [*insert date 10 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

SUPPLEMENTARY INFORMATION: EVSCO Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310, has requested that FDA withdraw approval of NADA 32-984 for Cerumite (chloramphenicol, prednisolone, tetracaine, and squalane) topical suspension, and NADA 55-005 for Liquichlor with Cerumene (squalane, pyrethrins, and piperonyl butoxide) topical suspension because the products are no longer manufactured or marketed. As provided below, the animal drug regulations are amended to reflect the withdrawal of approval of these NADAs by removing 21 CFR 524.390c and 524.2140.

In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

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 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:

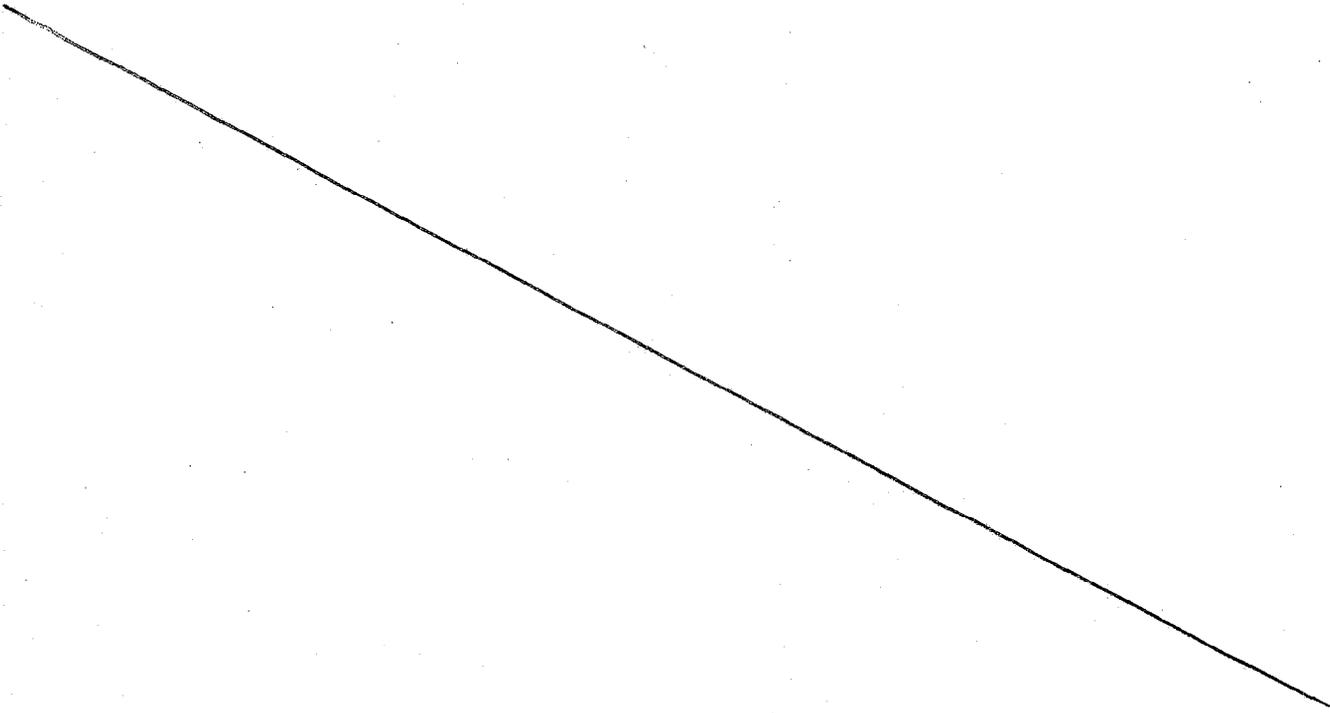
PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.390c [Removed]

2. Section 524.390c *Chloramphenicol-prednisolone-tetracaine-squalane topical suspension* is removed.



§ 524.2140 [Removed]

3. Section 524.2140 *Squalane, pyrethrins and piperonyl butoxide* is removed.

Dated: 8/6/01
August 6, 2001.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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