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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; 2-Mercaptobenzothiazole Solution

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 new animal drug application (NADA) filed by Combe, Inc. The supplemental NADA provides for the topical use of 2-mercaptobenzothiazole solution as an aid in the treatment of certain common skin inflammations in dogs.

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

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604, filed a supplement to NADA 5-236 that provides for the use of Sulfodene® (2-mercaptobenzothiazole) skin medication for dogs as an aid in the treatment of hot spots (moist dermatitis) and as first aid for scrapes and abrasions. The supplemental NADA provides for revisions to labeling. The NADA is approved as of July 3, 2000, and the regulations in 21 CFR 524.1376 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of any safety or effectiveness data. Therefore, a freedom of information summary is not required.

NADA - 005 - 236

NFR-1

The agency has determined under 21 CFR 25.33(d)(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.

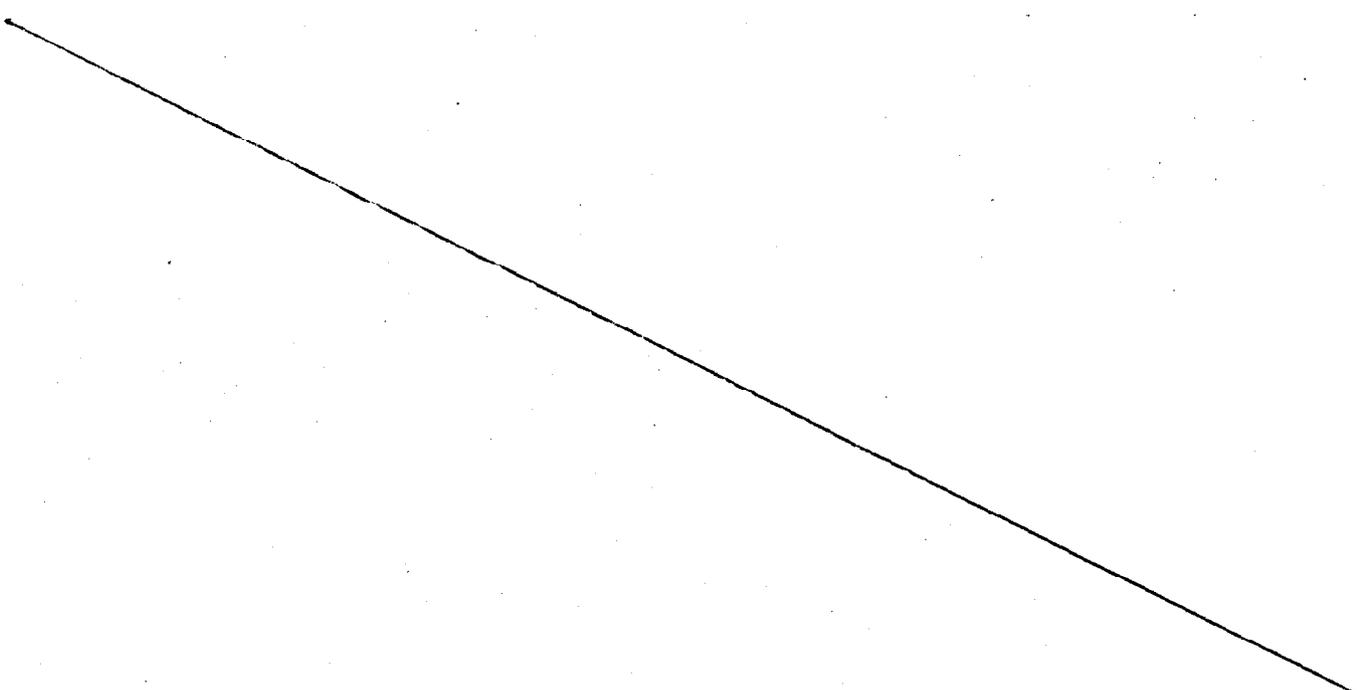
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

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.

§ 524.1376 [Amended]



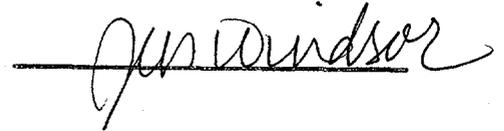
2. Section 524.1376 *2-Mercaptobenzothiazole solution* is amended in paragraph (c)(2) by removing the phrase “treating moist dermatitis and hot spots” and by adding in its place the phrase “the treatment of hot spots (moist dermatitis)”.

Dated: 7/21/00
July 21, 2000



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

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



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