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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier Jen Cooke

Food and Drug Administration

21 CFR Parts 510 and 524

1738 '03 JUN -3 A7:55

**New Animal Drugs; Change of Sponsor**

**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 a change of sponsor for an approved new animal drug application (NADA) from Combe, Inc., to Farnham Companies, Inc.

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

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967; e-mail: dnewkirk@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 5-236 for SULFODENE Medication for Dogs to Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013-3928.

Accordingly, the agency is amending the regulations in 21 CFR 524.1376 to reflect the transfer of ownership.

Following this change of sponsorship, Combe, Inc., is no longer the sponsor of any approved application. Accordingly, § 510.600(c) is being amended to remove the entries for Combe, Inc.

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**NADA 5-236**

**NFR1**

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

### *21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

### *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 parts 510 and 524 are amended as follows:

## **PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

### **§510.600 [Amended].**

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Combe, Inc.” and in the table in paragraph (c)(2) by removing the entry for “011509”.

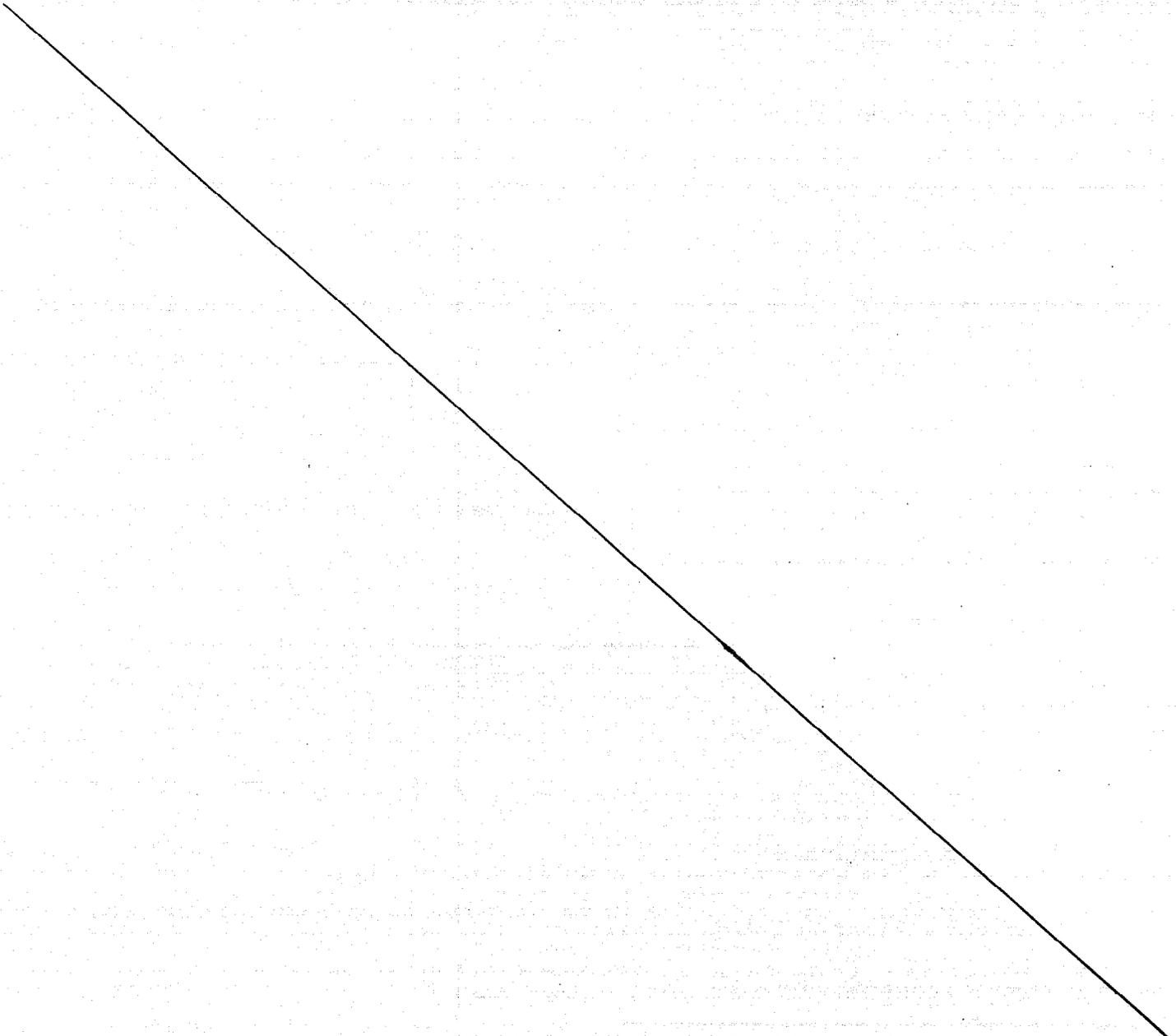
**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL  
DRUGS**

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

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

**§ 524.1580b [Amended]**

4. Section 524.1376 *2-Mercaptobenzothiazole solution* is amended in paragraph (b) by removing “011509” and by adding in its place “No. 017135”.



Dated: May 19, 2003  
May 16, 2003.

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[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Jim Cooke