DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Copper Naphthenate 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 Farnam Companies, Inc. The supplemental NADA provides for a revised food safety warning on labeling for copper naphthenate topical solution for horse and pony hooves.

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, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928, filed a supplement to NADA 100–616 for THRUSH-XX (copper naphthenate), a solution approved for topical use on horse and pony hooves as an aid in treating thrush. The supplemental NADA provides for a revised food safety warning on the labeling. The supplemental NADA is approved as of May 30, 2006, and the regulations are amended in 21 CFR 524.463 to reflect the approval and a current format.

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

The agency has determined under 21 CFR 25.33(d)(3) 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.

■ 2. In § 524.463, revise the section and paragraph (c) headings, and paragraphs (a) and (c)(3) to read as follows:

§ 524.463 Copper naphthenate.

(a) *Amount*. The drug is a 37.5 percent solution of copper naphthenate.

* * * * *

(c) *Conditions of use in horses*—* * *

* * * * *

(3) *Limitations*. Use on horses and ponies only. Avoid contact around eyes. Do not contaminate feed. Do not use in horses intended for human consumption.

Dated: June 22, 2006.

Steven D. Vaughn,

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

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