**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (ANADA) filed by IVX Animal Health, Inc. The ANADA provides for veterinary prescription use of griseofulvin powder orally as a systemic antifungal agent in horses.

**DATES:** This rule is effective July 5, 2006.

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200–391 that provides for veterinary prescription use of Griseofulvin Powder Microsize, orally as a systemic antifungal agent in horses. IVX Animal Health's Griseofulvin Powder Microsize, is approved as a generic copy of Schering-Plough Animal Health Corp.'s FULVICIN–U/F (griseofulvin) Powder approved under NADA 39–792. The ANADA is approved as of June 1, 2006, and the regulations are amended in 21 CFR 520.1100 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

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 520**

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 520 is amended as follows:

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Amend § 520.1100 as follows:

■ a. Revise paragraphs (a), (b), (c), and (d)(1);

■ b. Remove paragraphs (d)(2) and (d)(3)(iii); and

■ c. Redesignate paragraphs (d)(3) introductory text, (d)(3)(i), (d)(3)(i)(*a*), (d)(3)(i)(*b*), and (d)(3)(ii) as paragraphs (d)(2) introductory text, (d)(2)(i), (d)(2)(i)(A), (d)(2)(i)(B), and (d)(2)(ii).

The revisions read as follows:

**§ 520.1100 Griseofulvin.**

(a) *Specifications*—(1) The powder complies with U.S.P. for griseofulvin, microsize.

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 059130 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

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

(d) *Conditions of use*—(1) *Horses*—(i) *Amount and indications for use*—(A) For equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of this section daily for not less than 10 days as follows: adults, 1 bolus; yearlings, one-half to 1 bolus; and foals, one-half bolus.

(ii) *Limitations.* Not for use in horses intended for food.

* * * * *

Dated: June 23, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E6–10406 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

## 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 July 5, 2006.

**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.*

[FR Doc. E6–10407 Filed 7–3–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 9271]**

**RIN 1545–BB68**

## Effect of Elections in Certain Multi-Step Transactions

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations that give effect to section 338(h)(10) elections in certain multi-step transactions. These final regulations are necessary in order to provide taxpayers with guidance regarding the validity of certain elections made under section 338(h)(10). These final regulations affect corporations and their shareholders.

**DATES:** *Effective Date:* These regulations are effective July 5, 2006.

*Applicability Date:* For dates of applicability, see § 1.338(h)(10)–1(h) of these regulations.

**FOR FURTHER INFORMATION CONTACT:** Daniel F. Heins, at (202) 622–7930 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Background

The IRS published temporary regulations (TD 9071) in the **Federal Register** on July 9, 2003 (68 FR 40766) (the temporary regulations), along with a notice of proposed rulemaking by cross-reference to the temporary regulations (REG–143679–02) (the proposed regulations). These temporary regulations provide, notwithstanding anything to the contrary in § 1.338–3(c)(1)(i), a section 338(h)(10) election may be made for T where P's acquisition of T stock, viewed independently, constitutes a qualified stock purchase and, after the stock acquisition, T merges or liquidates into P (or another member of the affiliated group that includes P), whether or not, under relevant provisions of law, including the step transaction doctrine, the acquisition of the T stock and the merger or liquidation of T qualify as a reorganization described in section 368(a). If a section 338(h)(10) election is made in a case where the acquisition of T stock followed by a merger or liquidation of T into P qualifies as a reorganization described in section 368(a), for all Federal tax purposes, P's acquisition of T stock is treated as a qualified stock purchase and is not treated as part of a reorganization described in section 368(a). For rules about the operation of the step transaction doctrine and the relationship between section 338 and the reorganization provisions when a section 338 election is not made, see § 1.338–3(d). See also Rev. Rul. 90–95 (1990–2 CB 67). See § 601.601(d)(2).

No public hearing regarding the proposed regulations was requested or held. The IRS received written and electronic comments regarding the proposed regulations. After consideration of the comments, the proposed regulations are adopted by this Treasury decision. The most significant comments received with respect to the proposed regulations are discussed in this preamble.

### Explanation of Provisions

*A. Section 338(g) Elections*

Some commentators recommend that the final regulations allow section 338(g) elections, as well as section 338(h)(10) elections, to turn off the step transaction doctrine in a multi-step transaction that constitutes a reorganization under section 368(a). Although a section 338(g) election is made by the purchasing corporation and the shareholders of the target corporation (target) do not consent to the election, one commentator states that the IRS will not be subject to whipsaw if the IRS provides regulations requiring the shareholders of the acquired corporation to treat the transaction consistently with the acquiring corporation's election, rather than as a reorganization under section 368(a).

The final regulations do not adopt the commentators' recommendation, and continue to turn off the step transaction doctrine only in the case of section 338(h)(10) elections. Extending the final regulations to section 338(g) elections would allow the acquiring corporation to unilaterally elect to treat the transaction, for all parties, as other than a reorganization under section 368(a). In light of potential whipsaw and other concerns, the final regulations continue to apply only to section 338(h)(10) elections, not section 338(g) elections.

*B. Corporate Purchaser Requirement*

One commentator suggests that § 1.338–3(b) be amended to clarify under what circumstances a corporation will be considered, for tax purposes, to have purchased the stock of target pursuant to section 338(d)(3).

Under § 1.338–3(b), an individual cannot make a qualified stock purchase of target. If an individual forms a corporation (new P) to acquire target stock, new P can make a qualified stock purchase of target if new P is considered, for tax purposes, to purchase the target stock. Facts that may indicate that new P does not purchase the target stock include new P's merging downstream into target, liquidating, or otherwise disposing of the target stock following the purported qualified stock purchase.

The IRS and Treasury Department are continuing to study whether any amendments to the portion of the regulations under section 338 related to the corporate purchaser requirement are appropriate.

### Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations do not have a significant economic impact on a substantial amount of small entities. The number of corporations affected is limited because section 338(h)(10) elections are made only in extraordinary circumstances, the sale of a business. Furthermore, these