

## 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for topical use of copper naphthenate solution on horses and ponies as an aid in treating thrush caused by organisms susceptible to copper naphthenate.

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

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-304 for PRITOX, a solution of copper naphthenate for topical application on horses and ponies as an aid in treating thrush caused by organisms susceptible to copper naphthenate. First Priority's PRITOX is approved as a generic copy of Ft. Dodge Animal Health's KOPERTOXY, approved under NADA 12-991. The ANADA is approved as of July 25, 2003, and 21 CFR 524.463 is amended to reflect the approval. 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 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.

**§ 524.463 [Amended]**

■ 2. Section 524.463 *Copper naphthenate solution* is amended in paragraph (b) by removing “*Sponsor*” and by adding in its place “*Sponsors*”; and by removing “000856 and 017135” and by adding in its place “000856, 017135, and 058829”.

Dated: September 15, 2003.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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

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