

information as possible: The port to which the questionable merchandise was shipped; the importers' names and/or the purchasers' names; the kind of merchandise at issue; and any information regarding the alleged deliberate removal of the paper country-of-origin label.

Further, intentionally passing off reproductions as antiques can be prosecuted as criminal fraud or as civil fraud in a lawsuit by a buyer.⁴⁷ Additionally, the Lanham Act provides injured persons with a private right of action against certain false or misleading representations regarding goods or false designation of origin, *e.g.*, reproductions being passed off as original items. 15 U.S.C. 1125. Further, a pattern or practice of significant affirmative misrepresentations or failure to disclose material information relating to reproductions passed off as originals may violate the FTC Act.⁴⁸

In addition to the deliberate removal of country-of-origin labels, many commenters suggested that the lack of truly permanent country-of-origin labels on reproductions can result in these reproductions inadvertently being passed off as originals in the secondary market. This could be addressed, at least in part, through greater enforcement of labeling requirements to the initial seller and through educational remedies.

The record indicates that there are many non-legal resources available to educate consumers about antiques and collectibles and thus reduce consumers' susceptibility to the practice of passing off. For example, several newsletters and hobby newspapers regularly warn and advise buyers of antiques and collectibles about reproductions of specific items and classes of items.⁴⁹ The comments also indicate that there are collector clubs for many categories of collectibles that provide members with similar information.⁵⁰ The

Commission staff will continue to explore whether there is a role for the Commission in these efforts to increase consumer awareness.

IV. Conclusion

The comments uniformly favor retention of the rule and state that there is a continuing need for the rule with regard to currently covered products, *i.e.*, imitation numismatic and political items; that the rule benefits consumers and the industry; that the rule does not impose substantial economic burdens; and that the benefits of the rule outweigh the minimal costs it imposes.

Although many comments recommended that the rule be expanded to cover all antiques and collectibles, the Commission does not have the authority under the Act to expand the rule in this manner. Furthermore, there are a variety of legal and non-legal resources that address many of the issues raised by the commenters favoring expansion of the rule's coverage. Accordingly, the Commission has determined to retain the current Rule and is terminating this review.

List of Subjects in 16 CFR Part 304

Hobbies, Labeling, Trade practices.

Authority: The Federal Trade Commission Act, 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04–4768 Filed 3–2–04; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Penicillin G Potassium in Drinking Water

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 an abbreviated new animal drug application (ANADA) filed by Vétoquinol N.–A., Inc. The ANADA provides for the use of penicillin G in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

DATES: This rule is effective March 3, 2004.

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.

SUPPLEMENTARY INFORMATION:

Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J0K 1H0, filed ANADA 200–307 that provides for use of Penicillin G Potassium, USP, in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*. Vétoquinol N.–A., Inc.'s Penicillin G Potassium, USP, is approved as a generic copy of Fort Dodge Animal Health's Penicillin G Potassium, USP, approved under NADA 55–060. The ANADA is approved as of January 29, 2004, and the regulations are amended in 21 CFR 520.1696b 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 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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. Section 520.1696b is amended by revising paragraph (b) to read as follows:

⁴⁷ Section 2–721 of the Uniform Commercial Code provides civil remedies for material misrepresentation and fraud in sales transactions.

⁴⁸ Section 5 of the FTC Act prohibits deceptive acts or practices in commerce. 15 U.S.C. 45. A deceptive act or practice is one that is likely to mislead consumers acting reasonably under the circumstances. As a matter of policy, however, the Commission does not generally intervene in individual disputes. For the most part, the instances of passing off described in the comments reflect specific individual transactions, rather than a pattern or practice of passing off. Where the Commission obtains evidence of such a pattern or practice, however, it may take action.

⁴⁹ *E.g.*, Antiques & Collectors Reproduction News, published by Mr. Mark Chervenka of Des Moines, Iowa.

⁵⁰ *E.g.*, NAC. This commenter noted that many collecting clubs have educational programs, such as newsletters, Web sites, seminars or workshops at club conventions, about reproductions.

§ 520.1696b Penicillin G potassium in drinking water.

* * * * *

(b) *Sponsors.* See Nos. 046573, 053501, 059130, 059320, and 061623 in § 510.600(c) of this chapter.

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Dated: February 23, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04-4653 Filed 3-2-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Diclazuril

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 new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing diclazuril and roxarsone to formulate two-way

combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective March 3, 2004.

FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600, e-mail: candres@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-223 for use of CLINACOX (diclazuril) and 3-NITRO (roxarsone) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for broiler chickens. The NADA is approved as of January 27, 2004, and the regulations are amended in 21 CFR 558.198 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)(2) 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.198 is amended in the table in paragraph (d)(1) by redesignating paragraphs (d)(1)(vi) and (d)(1)(vii) as paragraphs (d)(1)(vii) and (d)(1)(viii), respectively, and by adding new paragraph (d)(1)(vi) to read as follows:

§ 558.198 Diclazuril.

* * * * *

(d) * * *

(1) * * *

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(vi) 0.91(1 ppm)	Roxarsone 22.7 to 45.4	Broiler chickens: As in item (i) of this table; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Roxarsone provided by No. 046573 in § 510.600(c) of this chapter.	046573
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