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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 [*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.*

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:

§ 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: Feb 23, 2004
February 23, 2004.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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