

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DPM

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Certifier A. Corbin

Implantation or Injectable Dosage Form New Animal Drugs; Ampicillin Sodium

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 G. C. Hanford Manufacturing Co. The ANADA provides for the use of ampicillin sodium powder in aqueous solution by injection in horses for the treatment of various bacterial infections.

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

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201, filed ANADA 200-335 that provides for use of ampicillin sodium as a constituted solution by injection in horses for the treatment of various bacterial infections. G. C. Hanford Manufacturing Co.'s Ampicillin Sodium is approved as a generic copy of Pfizer, Inc.'s, AMP-EQUINE, approved under NADA 55-084. The ANADA is approved as of July 12, 2007, and the regulations are amended in 21 CFR 522.90c to reflect the approval and a

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NFR 1

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.

FDA 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION AND INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Revise § 522.90c to read as follows:

§ 522.90c Ampicillin sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 000069 and 010515 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount:* 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) *Indications for use.* For the treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Streptococcus* spp. (including *S. equi*), *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(3) *Limitations.* Do not use in horses intended for human consumption.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 8/1/07
August 1, 2007.



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