

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier L. CLAWSON
DDM

Implantation or Injectable Dosage Form New Animal Drugs; Spectinomycin Sulfate

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 Pharmacia & Upjohn Co., a Div. of Pfizer, Inc. The supplemental NADA provides for revising nomenclature for two bovine respiratory pathogens on labeling for spectinomycin sulfate injectable solution.

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

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Div. of Pfizer, Inc., 235 E. 42d St., New York, NY 10017, filed a supplement to NADA 141-077 for ADSPEC (spectinomycin sulfate) Sterile Solution used for the treatment of bovine respiratory disease associated with several bacterial pathogens. The supplemental NADA provides for revising nomenclature for two bacterial pathogens on product labeling. The supplemental NADA is approved as of May 10, 2007, and the regulations in 21 CFR 522.2121 are amended 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(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 OR 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 § 522.2121 to read as follows:

§ 522.2121 Spectinomycin sulfate.

(a) *Specifications.* Each milliliter of solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams (mg) spectinomycin.

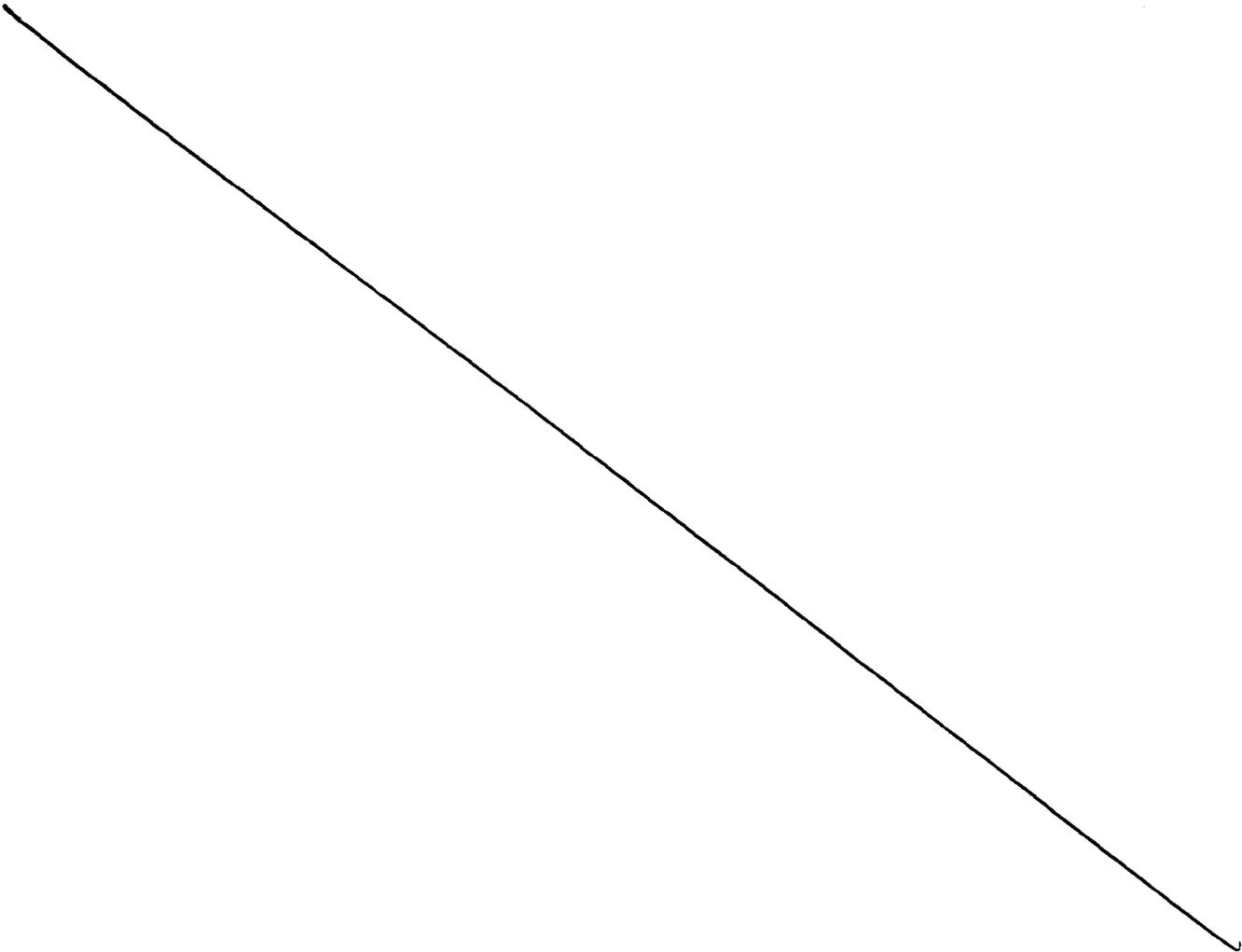
(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 10 to 15 mg per kilogram of body weight at 24-hour intervals for 3 to 5 consecutive days.

(2) *Indications for use.* For the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

(3) *Limitations.* Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for



this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 5/24/2007
May 24, 2007.

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5/30/07

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