

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DDM

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Forms; Cephapirin 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 supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADAs provide for revisions to the labeling of two cephalosporin sodium products administered by intramammary infusion to lactating cows for the treatment of mastitis.

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, 240-276-8342, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplements to NADA 97-222 that revise labeling of CEFA-LAK (cephapirin sodium) and TODAY (cephapirin sodium) Intramammary Infusion administered to lactating cows for the treatment of mastitis. The application is approved as of December 20, 2007, and the regulations are amended in 21 CFR 526.365 to reflect the approval and a current format.

cv07103

2008-97-222

NFR 3

Approval of these supplemental NADAs did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 526

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 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 1. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 2. In § 526.365, revise the section heading and paragraph (d) to read as follows:

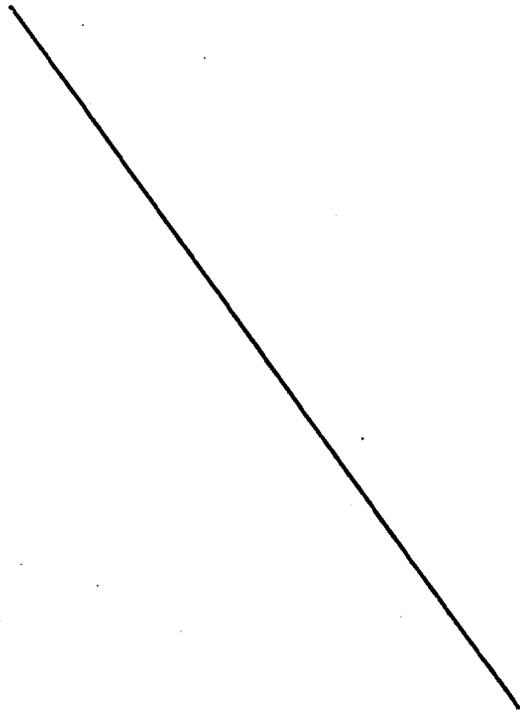
§ 526.365 Cephapirin sodium.

* * * * *

(d) *Conditions of use in lactating cows—(1) Amount.* Infuse one dose into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

(2) *Indications for use.* For the treatment of mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus* including strains resistant to penicillin.

(3) *Limitations.* If improvement is not noted within 48 hours after treatment, consult your veterinarian. Milk that has been taken from animals

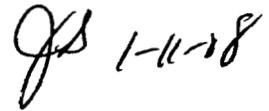


during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

Dated: 01/04/08
January 4, 2008.



Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.



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