Rules and Regulations

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 cephapirin sodium products administered by intramammary infusion to lactating cows for the treatment of mastitis.

DATES: This rule is effective January 17, 2008.

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.

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: January 4, 2008.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E8–816 Filed 1–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 13

RIN 1024–AD38

National Park System Units in Alaska

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: This rule revises the special regulations for the NPS-administered areas in Alaska to update provisions governing subsistence use of timber, river management, ORV use, fishing, and camping. The revision also updates definitions, prohibits pets in certain areas, and establishes wildlife viewing distances in several park areas.

DATES: This rule is effective on February 19, 2008.

FOR FURTHER INFORMATION CONTACT: National Park Service, Victor Knox, Deputy Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501. Telephone: (907) 644–3501. E-mail: *akro_regulations@nps.gov*. Fax: (907) 644–3816.

SUPPLEMENTARY INFORMATION:

Background

On December 27, 2006, the NPS published in the **Federal Register** proposed revised special regulations for the NPS-administered areas in Alaska. Each park area in Alaska has a compendium consisting of the compiled designations, closures, openings, permit requirements, and other provisions established by the Superintendent under the discretionary authority granted in 36 CFR 1.5 and elsewhere in regulations. It is the policy of the NPS to review these provisions on a regular basis for possible addition to the general and special park regulations in part 13. The provisions in this final rule are additions or changes to individual park regulations in part 13, subparts H–W. Where these provisions have applicability to several or all Alaska