Rules and Regulations

Federal Register
Vol. 73, No. 3
Friday, January 4, 2008

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Form New Animal Drugs; Pirlimycin

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 and Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA extends the dosage regimen for pirlimycin hydrochloride intramammary infusion in lactating dairy cattle to daily treatment for up to 8 days.

DATES: This rule is effective January 4, 2008.

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 Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–036 that provides for veterinary prescription use of PIRSUE (pirlimycin hydrochloride) Sterile Solution in lactating dairy cattle for the treatment of mastitis. The supplement extends the dosage regimen to daily treatment for up to 8 days. The supplemental NADA is approved as of December 12, 2007, and the regulations are amended in 21 CFR 526.1810 to reflect the approval.

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33(d)(5) 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 the 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 FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 526.1810, revise the section heading and paragraphs (a), (b), and (d) to read as follows:

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

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

* * * * *

(d) *Conditions of use in cattle*—(1) *Amount.* Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use.* For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–25606 Filed 1–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Semduramicin

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 new animal drug application (NADA) filed by Phibro Animal Health. The NADA provides for use of a Type A medicated article containing semduramicin (as semduramicin sodium biomass) to manufacture Type C medicated broiler chicken feed for the prevention of coccidiosis.

DATES: This rule is effective January 4, 2008.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary