

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid

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 Pharmacia & Upjohn Co. The NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in beef and nonlactating dairy cattle, by subcutaneous injection in the ear, for the treatment and control of bovine respiratory disease (BRD).

DATES: This rule is effective October 22, 2003.

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: jgotthar@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed NADA 141-209 for NAXCEL XT (ceftiofur crystalline free acid) Sterile Suspension. The NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in beef and nonlactating dairy cattle, by subcutaneous injection in the ear, for the treatment of BRD (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus* and for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus*. The application is approved as of September 5, 2003, and the regulations are amended in 21 CFR part 522 by adding new § 522.315 to reflect the approval. In addition, 21 CFR 556.113 is being amended to add an acceptable single-dose intake for residues of ceftiofur at the injection site and a tolerance for residues at the injection site. 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 5, 2003.

The agency 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 522 and 556 are 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. Section 522.315 is added to read as follows:

§ 522.315 Ceftiofur crystalline free acid.

(a) *Specifications.* Each milliliter of suspension contains 200 milligrams (mg) ceftiofur equivalents (CE).

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

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 6.6 mg CE per kilogram of body weight by a single, subcutaneous injection in the middle third of the posterior aspect of the ear.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia)

associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.113 is amended by redesignating paragraph (a) as paragraph (a)(1); by adding a new header to paragraph (a); by adding new paragraph (a)(2); and by adding a new sentence to the end of paragraph (b)(2) to read as follows:

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake and acceptable single-dose intake*—(1) *Acceptable daily intake (ADI).* * * *

(2) *Acceptable single-dose intake (ASDI).* The ASDI total residues of ceftiofur is 0.830 milligrams per kilogram of body weight. The ASDI is the amount of total residues of ceftiofur that may safely be consumed in a single meal. The ASDI is used to derive the tolerance for residues of desfuroylceftiofur at the injection site.

(b) * * *

(1) * * *

(2) * * * The tolerance for residues of desfuroylceftiofur in injection site muscle is 166 parts per million.

Dated: October 2, 2003.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9093]

RIN 1545-AX39

Special Rules for Certain Foreign Business Entities

AGENCY: Internal Revenue Service (IRS), Treasury.