Rules and Regulations

Federal Register
Vol. 73, No. 100
Thursday, May 22, 2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Cefovecin

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 Pfizer, Inc. The NADA provides for the veterinary prescription use of a solution of cefovecin sodium in cats and dogs by subcutaneous injection for the treatment of skin infections.

DATES: This rule is effective May 22, 2008.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–285 that provides for the veterinary prescription use of CONVENIA (cefovecin sodium) Injectable in cats and dogs by subcutaneous injection for the treatment of skin infections. The application is approved as of April 25, 2008, and the regulations are amended in 21 CFR part 522 to reflect 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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.

§ 522.311 [Redesignated as § 522.300]

■ 2. Redesignate § 522.311 as § 522.300.

§ 522.312 [Redesignated as § 522.304]

■ 3. Redesignate § 522.312 as § 522.304.

■ 4. Add new § 522.311 to read as follows:

§ 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount.* Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

Dated: May 13, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–11515 Filed 5–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–275F]

RIN 1117–AA99

Changes to Patient Limitation for Dispensing or Prescribing Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment by Qualified Individual Practitioners

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: On September 20, 2007, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (72 FR 53734) proposing to conform its regulations to recent statutory amendments to the Controlled Substances Act that changed certain patient limitations for practitioners who dispense or prescribe certain narcotic drugs for maintenance or detoxification treatment. DEA received one comment in support of this rulemaking. DEA is finalizing the rule as proposed.

DATES: *Effective Date:* This rule is effective June 23, 2008.