

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Maropitant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DDM
Display Date 2-28-07
Publication Date 3-1-07
Certifier N. Hawkins

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two new animal drug applications (NADAs) filed by Pfizer, Inc. The NADAs provide for the veterinary prescription use of maropitant citrate tablets and maropitant citrate injectable solution for the management of vomiting in dogs.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141-262 for CERENIA (maropitant citrate) Tablets. The NADA provides for the veterinary prescription use of maropitant citrate tablets in dogs for the prevention of acute vomiting and for the prevention of vomiting due to motion sickness. The application is approved as of January 29, 2007, and 21 CFR part 520 is amended by adding new § 520.1315 to reflect the approval.

Pfizer, Inc., also filed NADA 141-263 for CERENIA (maropitant citrate) Injectable Solution, used by veterinary prescription in dogs for the prevention

and treatment of acute vomiting. The application is approved as of January 29, 2007, and 21 CFR part 522 is amended by adding new § 522.1315 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), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this original approval of NADA 141-262 qualifies for 5 years of marketing exclusivity beginning January 29, 2007.

Under section 512(c)(2)(F)(ii) of the act, this original approval of NADA 141-263 qualifies for 3 years of marketing exclusivity beginning January 29, 2007.

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 Parts 520 and 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 parts 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

- 2. Section 520.1315 is added to read as follows:

§ 520.1315 Maropitant.

(a) *Specifications.* Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

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

(c) *Conditions of use in dogs—(1) Indications for use and amount.* For the prevention of acute vomiting, administer a minimum of 2.0 mg per kilogram (/kg) body weight once daily for up to 5 consecutive days. For the prevention of vomiting due to motion sickness, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

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

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

- 4. Section 522.1315 is added to read as follows:

§ 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

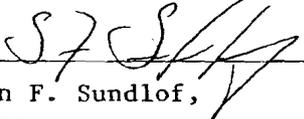
(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 1.0 mg per kilogram body weight by subcutaneous injection once daily for up to 5 consecutive days.

(2) *Indications for use.* For the prevention and treatment of acute vomiting.

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

Dated: 2/16/07
February 16, 2007.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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