

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Meloxicam

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 two supplemental new animal drug applications (NADAs) filed by Boehringer Ingelheim Vetmedica, Inc. The first supplemental NADA provides for use of meloxicam injectable solution in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery. It also provides revised dosage labeling for this product in dogs. The other supplemental NADA provides revised dosage labeling for use of meloxicam oral suspension in dogs.

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

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SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506-2002, filed a supplement to NADA 141-219 that provides for use of METACAM (meloxicam) Solution for Injection in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered

prior to surgery, and also revises dosage information for use of this product in dogs. Boehringer Ingelheim Vetmedica, Inc., also filed a supplement to NADA 141–213 that provides revised dosage information for use of METACAM (meloxicam) Oral Suspension in dogs. The supplemental NADAs are approved as of October 28, 2004, and the regulations are amended in 21 CFR 520.1350 and 522.1367 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

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)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), the supplemental approval of meloxicam injectable solution for use in cats qualifies for 3 years of marketing exclusivity beginning October 28, 2004.

The agency has determined under 21 CFR 25.33(d)(5) 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 520.1350 is amended by revising paragraph (c)(1) to read as follows:

§ 520.1350 Meloxicam.

* * * * *

(c) * * *

(1) *Amount.* Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

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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 522.1367 is amended by revising paragraph (c) to read as follows:

§ 522.1367 Meloxicam.

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(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

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

(2) *Cats*—(i) *Amount*. Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

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

Dated: November 18, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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