## 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. Add § 522.870 to read as follows:

**§ 522.870 Etodolac.**

(a) *Specifications.* Each milliliter contains 100 milligrams (mg) etodolac.

(b) *Sponsor.* See No. 000856 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 4.5 to 6.8 mg/pound (10 to 15 mg/kilogram) body weight as a single, dorsoscapular subcutaneous injection. If needed, the daily dose of etodolac tablets as in § 520.870 of this chapter may be given 24 hours after the injection.

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

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

Dated: August 28, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7–17645 Filed 9–6–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs; Dexmedetomidine

**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 Orion Corp. The supplemental NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a sedative and analgesic in cats.

**DATES:** This rule is effective September 7, 2007.

**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:** Orion Corp., Orionintie 1, 02200 Espoo, Finland, filed a supplement to NADA 141–267 for DEXDOMITOR (dexmedetomidine hydrochloride). The supplemental NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a sedative and analgesic in cats. The supplemental application is approved as of August 15, 2007, and the regulations in 21 CFR 522.558 are amended 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 the 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.

The agency has determined under 21 CFR 25.33(d)(1) 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.

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)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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.

■ 2. In § 522.558, revise paragraph (c) to read as follows:

**§ 522.558 Dexmedetomidine.**

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount.* (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (µg) per square meter (/$m^2$) of body surface area by intravenous injection or 500 µg/$m^2$ of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 µg/$m^2$ of body surface area or 375 µg/$m^2$ of body surface area by intramuscular injection.

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

(2) *Cats*—(i) *Amount.* 40 µg/killogram by intramuscular injection.

(ii) *Indications for use.* For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures.

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

Dated: August 28, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 60

**[EPA–HQ–OAR–2002–0071; FRL–8448–9]**

**RIN 2060–A009**

### Update of Continuous Instrumental Test Methods: Technical Amendments

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action on ''Update of Continuous Instrumental Test Methods: Technical Amendments'' to correct errors in a recent final rule that amended five instrumental test methods and was published on May 15, 2006. As published, the amendments contained inadvertent errors and provisions that need to be clarified. We are correcting errors and clarifying portions of the amendments to reflect the intent of the rule and to make them more understandable by affected parties.

**DATES:** This rule is effective on November 6, 2007 without further