

marketing exclusivity beginning December 12, 2006.

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.

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 520

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 520 is 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 520.666 is added to read as follows:

§ 520.666 Dirlotapide.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

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

(c) *Conditions of use in dogs—(1) Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

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

Dated: December 20, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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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 an original new animal drug application (NADA) filed by Orion Corp. The NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a sedative, analgesic, and preanesthetic in dogs.

DATES: This rule is effective January 4, 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 NADA 141–267 for DEXDOMITOR (dexmedetomidine hydrochloride). The NADA provides for the veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a sedative, analgesic, and preanesthetic in dogs. The application is approved as of December 1, 2006, and 21 CFR part 522 is amended by adding new § 522.558 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), 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.

The agency has determined under § 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)(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 December 1, 2006.

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 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. Add § 522.558 to read as follows:

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) dexmedetomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Indications for use and amount—(i)* For use as a sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (µg) per square meter (m²) of body surface area by intravenous injection or 500 µg/m² of body surface area by intramuscular injection.

(ii) For use as a preanesthetic to general anesthesia, administer 125 µg/m² of body surface area or 375 µg/m² of body surface area by intramuscular injection.

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

Dated: December 19, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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