

700 feet or more above the surface of the earth is expanded from within a 6.5-mile radius to within a 7.6-mile radius of the airport. This will accommodate aircraft executing new SIAPs at Poplar Bluff Municipal Airport. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA order 7400.9P, dated September 1, 2006, and effective September 15, 2006, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under this section, the FAA is charged with prescribing regulations to assign the use of the of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace.

This regulation is within the scope of that authority since it improves the safety of aircraft executing IFR procedures at Poplar Bluff Municipal Airport, Poplar Bluff, MO.

List of Subjects in CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9P, dated September 1, 2006, and effective September 15, 2006, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE MO E5 Poplar Bluff, MO [Amended]

Poplar Bluff Municipal Airport, MO
(Lat. 36°26'26" N., long. 90°19'29" W.)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of Poplar Bluff Municipal Airport, and within 2.6 miles each side of the 181° bearing from the Poplar Bluff Municipal Airport extending from the 7.6-mile radius, to 7.6 miles south of the airport.

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Issued in Forth Worth, TX, on August 28, 2004.

Roger M. Trevino,

*Manager, System Support Group, ATO
Central Service Center.*

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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; Etodolac

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 Fort Dodge Animal Health, Division of Wyeth. The NADA provides for veterinary

prescription use of etodolac injectable solution in dogs for the control of pain and inflammation associated with osteoarthritis.

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: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501 filed NADA 141–274 that provides for veterinary prescription use of ETOGESIC (etodolac) Injectable in dogs for the control of pain and inflammation associated with osteoarthritis. The application is approved as of August 16, 2007, and part 522 (21 CFR part 522) is amended by adding § 522.870 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.

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 on the date of approval.

FDA 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 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 § 522.870 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]

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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 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 (/m²) of body surface area by intravenous injection or 500 µg/m² of body surface area by intramuscular injection.

(B) 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.

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

(2) *Cats—(i) Amount.* 40 µg/kilogram 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.

[FR Doc. E7-17696 Filed 9-6-07; 8:45 am]

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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