DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Atipamezole

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 adds a claim for reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride to labeling for atipamezole hydrochloride injectable solution for 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 a supplement to NADA 141–033 for ANTISEDAN (atipamezole hydrochloride), an injectable solution approved for reversal of the sedative and analgesic effects of medetomidine hydrochloride in dogs. The supplemental NADA adds a claim for reversal of sedative and analgesic effects of dexmedetomidine hydrochloride to labeling for atipamezole hydrochloride injectable solution for dogs. The application is approved as of December 1, 2006, and the regulations are amended in 21 CFR 522.147 to reflect the approval and a current format.

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 (21 U.S.C. 360b(c)(2)(F)(iii)), 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. In § 522.147, revise the section heading and paragraphs (a) and (c) to read as follows:

§ 522.147 Atipamezole.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams atipamezole hydrochloride.

* * * * *

(c) *Conditions of use in dogs*—(1) *Amount.* Inject intramuscularly the same volume as that of dexmedetomidine or medetomidine used.

(2) *Indications for use.* For reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride or medetomidine hydrochloride.

(3) *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.

[FR Doc. E6–22515 Filed 1–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Chlorhexidine

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 Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for a revised food safety warning on labeling for chlorhexidine ointment.

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: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 9–782 for NOLVASAN (chlorhexidine acetate) Antiseptic Ointment, approved as a topical antiseptic for superficial wounds of dogs, cats, and horses. The supplemental NADA provides for a revised food safety warning on labeling. The supplemental application is approved as of November 28, 2006, and the regulations are amended in 21 CFR 524.402 to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Revise § 524.402 to read as follows:

§ 524.402 Chlorhexidine.

(a) *Specifications.* Each gram of ointment contains 10 milligrams chlorhexidine acetate.

(b) *Sponsors.* See Nos. 000856 and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs, cats, and horses*—(1) *Indications for use.* For use as a topical antiseptic ointment for surface wounds.

(2) *Limitations.* Do not use in horses intended for human consumption.

Dated: December 19, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–22514 Filed 1–3–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2006–0577–200620(a); FRL–8265–4]

Approval and Promulgation of Implementation Plans; Tennessee: Approval of Revisions to the Knox County Portion of the Tennessee State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Tennessee State Implementation Plan (SIP) submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), on January 20, 2006. The revisions pertain to the Knox County portion of the Tennessee SIP, and include changes to the Knox County Air Quality Regulations (KCAQR) Section 46.0—''Regulation of Volatile Organic Compounds.'' The changes were made following EPA action on the corresponding federal law. The changes add four compounds to the list of compounds excluded from the definition of volatile organic compounds (VOC) on the basis that they make a negligible contribution to ozone formation. This action is being taken pursuant to section 110 of the Clean Air Act (CAA).

DATES: This direct final rule is effective March 5, 2007 without further notice, unless EPA receives adverse comment by February 5, 2007. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2006–0577 by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail*: *louis.egide@epa.gov*.

3. *Fax*: (404) 562–9019.

4. *Mail*: ''EPA–R04–OAR–2006–0577,'' Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier*: Dr. Egide Louis, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R04–OAR–2006–0577. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Egide Louis, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9240. Dr. Louis can also be reached via electronic mail at *louis.egide@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Today's Action

On January 20, 2006, the State of Tennessee, through TDEC, submitted revisions to the Knox County portion of the Tennessee SIP to include changes to KCAQR Section 46.0—''Regulation of Volatile Organic Compounds.'' The change adds four compounds to the list