DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Firocoxib Paste

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 Merial Ltd. The NADA provides for veterinary prescription use of firocoxib oral paste in horses for the control of pain and inflammation associated with osteoarthritis.

DATES: This rule is effective February 3, 2006.

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.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed NADA 141–253 for veterinary prescription use of EQUIOXX (firocoxib) oral paste for the control of pain and inflammation associated with osteoarthritis in horses. The NADA is approved as of December 30, 2005, and 21 CFR part 520 is amended by adding new § 520.930 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 December 30, 2005.

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. Revise the section heading of § 520.928 to read as follows:

§ 520.928 Firocoxib tablets.

*   *   *   *   *

■ 3. Add § 520.930 to read as follows:

§ 520.930 Firocoxib paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.82 mg firocoxib.

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 0.1 mg per kilogram (0.045 mg per pound) body weight daily for up to 14 days.

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

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 18, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–993 Filed 2–2–06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–06–009]

RIN 1625–AA00

Security Zone; Choptank River, Cambridge, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone from February 9 through February 12, 2006, encompassing certain waters of the Choptank River. This action is necessary to ensure the safety of persons and property, and prevent terrorist acts or incidents during the U.S. House Republican Issues Conference. This rule prohibits vessels and people from entering the security zone and requires vessels and persons in the security zone to depart the security zone, unless specifically exempt under the provisions in this rule or granted specific permission from the Coast Guard Captain of the Port Baltimore.

DATES: This rule is effective from 7 a.m. eastern standard time on February 9, 2006 through 7 a.m. eastern standard time on February 12, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–06–009 and are available for inspection or copying at Commander, Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Baltimore, Maryland 21226–1791, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald Houck, Waterways Management Division, at Commander, Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Baltimore, Maryland 21226–1791, telephone number (410) 576–2674.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard is establishing this security zone to support the United States Capitol Police Dignitary Protection Division, the lead federal agency coordinating security for the U.S. House Republican Issues Conference, in their efforts to coordinate security operations and establish a secure environment for this highly visible and publicized event. This temporary security zone of short duration is necessary to provide for the security of a large gathering of high-ranking United States officials, their families and staff. Additionally, the publication of an NPRM is contrary to the public interest as our nation continues its heightened security posture. Therefore, immediate action is