DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2008–N–0039]

Oral Dosage Form New Animal Drugs; Firocoxib Tablets

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 Merial Ltd. The supplemental NADA provides for veterinary prescription use of firocoxib chewable tablets in dogs for the control of postoperative pain and inflammation associated with orthopedic surgery.

DATES: This rule is effective October 31, 2008.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 141–230 for PREVICOX (firocoxib) Chewable Tablets. The supplemental application provides for the veterinary prescription use of firocoxib chewable tablets in dogs for the control of postoperative pain and inflammation associated with orthopedic surgery. The NADA is approved as of September 23, 2008, and the regulations in 21 CFR 520.928 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), 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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. In § 520.928, revise paragraphs (c)(1) and (c)(2) to read as follows:

§ 520.928 Firocoxib tablets.

* * * * *

(c) * * *

(1) *Amount.* 5 mg/kg (2.27 mg/lb) body weight. Administer once daily for osteoarthritis. Administer approximately 2 hours before soft-tissue or orthopedic surgery.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis; and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

* * * * *

Dated: October 17, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–26020 Filed 10–30–08; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 393

[Docket No. MARAD 2008 0096]

RIN 2133–AB70

America's Marine Highway Program, Corrections

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Correcting amendment.

SUMMARY: The Maritime Administration is correcting an interim final rule that appeared in the **Federal Register** of October 9, 2008 (73 FR 59530). Due to the current financial environment and the receipt of informal comments indicating that one hundred and twenty (120) days is insufficient time to formulate an application, this document changes the summary section of the regulation to reflect that the Maritime Administration is seeking comment on the America's Marine Highway program and recommendations for Marine Highway Corridors and not soliciting applications for specific projects at this time.

DATES: *Effective Date:* This final rule is effective November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Michael Gordon, Office of Intermodal System Development, Marine Highways and Passenger Services, at (202) 366–5468, via e-mail at *michael.gordon@dot.gov,* or by writing to the Office of Marine Highways and Passenger Services, MAR–520, Suite W21–315, 1200 New Jersey Avenue, SE., Washington, DC. 20590.

SUPPLEMENTARY INFORMATION:

In FR Doc. 2008–0096 appearing on page 59530 in the **Federal Register** of Thursday, October 9, 2008, the following corrections are made:

Summary [Corrected]

1. On page 59530, the first sentence is corrected to read ''The purpose of this interim final rule is to solicit recommendations for short sea transportation routes to be designated as Marine Highway Corridors and to seek further comment on the Marine Highway program as set forth in this regulation by section 55605(c) of Public Law 110–140, the Energy Independence and Security Act of 2007.''

Dated: October 23, 2008.

By order of the Maritime Administrator.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. E8–25958 Filed 10–30–08; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2249; MB Docket No. 08–148; RM–11474]

Television Broadcasting Services; Fort Worth, TX

AGENCY: Federal Communications Commission.