

**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](mailto: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.*

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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

required to address the ongoing threat to U.S. national interests.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The measures contemplated by the rule are intended to protect the public by preventing waterborne acts of terrorism, which terrorists have demonstrated a capability to carry out. Immediate action is needed to defend against and deter these terrorist acts. Any delay in the effective date of this rule is contrary to public and national interests.

### Background and Purpose

The U.S. Maritime Administration (MARAD) in Advisory 02-07 advised U.S. shipping interests to maintain a heightened state of alert against possible terrorist attacks. MARAD more recently issued Advisory 03-06 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. The ongoing hostilities in Afghanistan and Iraq have made it prudent for U.S. ports and waterways to be on a higher state of alert because the al Qaeda organization and other similar organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

Due to increased awareness that future terrorist attacks are possible the Coast Guard, as lead federal agency for maritime homeland security, has determined that the Coast Guard Captain of the Port must have the means to be aware of, deter, detect, intercept, and respond to asymmetric threats, acts of aggression, and attacks by terrorists on the American homeland while still maintaining our freedoms and sustaining the flow of commerce. This security zone is part of a comprehensive port security regime designed to safeguard human life, vessels, and waterfront facilities against sabotage or terrorist attacks.

The Captain of the Port is establishing a security zone to address the aforementioned security concerns and to take steps to prevent the catastrophic impact that a terrorist attack against a large gathering of high-ranking United States officials, their families, and staff at or near the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina would have. This temporary security zone applies to all waters of the Choptank River, within 500 yards of the resort's River Marsh Marina Breakwater Pavilion, in approximate position latitude 38°33.76' N longitude

076°02.75' W (North American Datum of 1983). Vessels underway at the time this security zone is implemented will immediately proceed out of the zone.

We will issue Broadcast Notices to Mariners to further publicize the security zone and any revisions to the zone. This security zone is issued under authority contained in 50 U.S.C. 191 and 33 U.S.C. 1226.

Except for Public vessels and vessels at berth, mooring or at anchor, this rule temporarily requires all vessels in the designated security zone as defined by this rule to depart the security zone.

### Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to operate or transit on the Choptank River, within 500 yards of the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina's Breakwater Pavilion, in approximate position latitude 38°33.76' N longitude 076°02.75' W (North American Datum of 1983). This security zone will not have a significant economic impact on a substantial number of small entities due to its limited size, vessels requiring to transit the federal navigation channel will be able to do so, and a lack of seasonal vessel traffic associated with recreational boating and commercial fishing during the effective period. Further, vessels with compelling interests that outweigh the port's security needs may be granted waivers

from the requirements of the security zone.

### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If your small business or organization would be affected by this final rule and you have questions concerning its provisions or options for compliance, please contact one of the points of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

### Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

### Federalism

A rule has implications for federalism under Executive Order 13132, federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### Taking of Private Property

This rule will not effect a taking of private property or otherwise have

taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

#### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### Environment

We have analyzed this rule under Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Vessels, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–009 to read as follows:

#### § 165.T05–009 Security Zone; Choptank River, Cambridge, Maryland.

(a) *Definitions.* For the purposes of this section:

(1) *Captain of the Port Baltimore* means the Commander, U.S. Coast Guard sector Baltimore, Maryland and any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Commander, U.S. Coast Guard Sector Baltimore, Maryland to act as a designated representative on his or her behalf.

(2) *State and/or local law enforcement officers* means any State or local government law enforcement officer who has the authority to enforce State criminal laws.

(b) *Location.* The following area is a security zone: All waters of the Choptank River, within 500 yards of the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina's Breakwater Pavilion, in approximate position latitude 38°33.76' N longitude 076°02.75' W (North American Datum of 1983).

(c) *Regulations.* (1) The general regulations governing security zones found in § 165.33 of this part apply to the security zone described in paragraph (b).

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore or his designated representative. Except for Public vessels and vessels at berth, mooring or at anchor, all vessels in this zone are to depart the security zone.

(3) Persons desiring to transit the area of the security zone must first obtain authorization from the Captain of the Port Baltimore. To seek permission to transit the area, the Captain of the Port Baltimore can be contacted at telephone number (410) 576–2693. The Coast Guard vessels enforcing this section can be contacted on VHF Marine Band Radio, VHF channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Effective period.* This section is effective from 7 a.m. eastern standard time on February 9, 2006 through 7 a.m. eastern standard time on February 12, 2006.

Dated: January 23, 2006.

**Curtis A. Springer,**

*Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.*

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