

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs; Etodolac 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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral veterinary prescription use of etodolac tablets for the management of pain and inflammation associated with osteoarthritis in dogs.

**EFFECTIVE DATE:** September 25, 1998.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1618.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, filed NADA 141-108 that provides for oral veterinary prescription use of Etogesic™ (etodolac) tablets for the management of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of July 22, 1998, and the regulations are amended by adding 21 CFR 520.870 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 21 U.S.C. 360b(c)(2)(F)(i), this approval qualifies for 5 years of marketing exclusivity beginning July 22, 1998, because no active ingredient of the drug, including any ester or salt of the active ingredient, has been previously approved in any other application filed under section 512(b)(1) of the act.

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.

**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. Section 520.870 is added to read as follows:

**§ 520.870 Etodolac.**

(a) *Specifications.* Each tablet contains 150 or 300 milligrams (mg) of etodolac.

(b) *Sponsor.* See 053501 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 10 to 15 mg per kilogram (4.5 to 6.8 mg/pound) of body weight per day.

(ii) *Indications for use.* For the management of pain and inflammation associated with osteoarthritis in dogs.

(iii) *Limitations.* Use once-a-day. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: August 27, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98-25639 Filed 9-24-98; 8:45 am]

**BILLING CODE 4160-01-F**

**DEPARTMENT OF JUSTICE****28 CFR Part 16****Production or Disclosure of Material or Information****CFR Correction**

In Title 28 of the Code of Federal Regulations, parts 0 to 42, revised as of July 1, 1998, page 217, § 16.3 paragraph (a), and page 234, § 16.41 paragraphs (a) and (c) the Government Printing Office's World Wide Web site is corrected to read "http://www.access.gpo.gov/su\_docs."

**BILLING CODE 1505-01-D**

**DEPARTMENT OF TRANSPORTATION****Coast Guard****33 CFR Part 117**

[CGD08-98-062 and CGD 08-98-052]

RIN 2115-AE47

**Drawbridge Operations Regulation; Lafourche Bayou, LA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary rule; withdrawal of temporary rule.

**SUMMARY:** The Coast Guard is temporarily changing the operation of the draw of the SR1 vertical lift bridge across Lafourche Bayou, mile 13.3, in Leeville, Lafourche Parish, Louisiana. From October 5, 1998, until November 5, 1998, the draw need not open for navigation from 8 a.m. until noon and from 1 p.m. until 6 p.m. on Mondays and from 7 a.m. until 7 p.m. on Tuesdays, Wednesdays, and Thursdays. Additionally, the draw may remain closed to navigation for two 48-hour periods on the weekends of October 10-12, 1998, and October 17-19, 1998. This temporary rule is issued to allow for the replacement of the electrical and mechanical components of the bridge. The previous temporary rule published on September 8, 1998, is withdrawn.

**DATES:** This temporary rule is effective from 8 a.m. on October 5, 1998 through 7 p.m. on November 5, 1998. The temporary rule published on September 8, 1998, (63 FR 47427) is withdrawn.

**ADDRESSES:** All documents referred to in this notice will be available for inspection and copying at room 1313 in the Hale Boggs Federal Building at Commander (ob), Eighth Coast Guard District, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130-3396 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary rule.

**FOR FURTHER INFORMATION CONTACT:** David Frank, Bridge Administration Branch, Commander (ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana, 70130-3396, telephone number 504-589-2965.

**SUPPLEMENTARY INFORMATION:** On September 8, 1998, a temporary rule was published in the **Federal Register** (63 FR 47427) requiring the draw of the SR 1 bridge, mile 13.3, at Leeville, to open on signal, except that; from noon on October 5, 1998, through noon on November 6, 1998, the draw may remain

closed to navigation continuously from noon on Mondays through noon on Fridays.

Following re-publication of the temporary rule in the Local Notice to Mariners, several shrimpers and shipyard owners expressed concerns that the proposed bridge closure would have an adverse economic hardship on them. A meeting was held with the Lafourche Parish Port Authority, the Louisiana Department of Transportation and Development (LDOTD), the contractor, shrimpers, shipyard owners, and the Coast Guard to attempt to modify the repair/maintenance work schedule and to make bridge operations more responsive to the needs of navigation.

At this meeting, a new schedule of work that could accomplish the needed maintenance and also would be less burdensome on navigation interests was agreed upon. The new schedule of work requires that from October 5, 1998, until November 5, 1998, the bridge shall open on signal except the bridge need not open for the passage of vessels from 8 a.m. until noon, and from 1 p.m. until 6 p.m. on Mondays and from 7 a.m. until 7 p.m. on Tuesdays, Wednesdays, and Thursdays. Additionally, the bridge need not open for the passage of vessels from 7 a.m. on Saturday, October 10, 1998, until 7 a.m. on Monday, October 12, 1998, and from 7 a.m. on Saturday, October 17, 1998, until 7 a.m. on Monday, October 19, 1998.

All parties agreed that one or two continuous 48-hour closures would be less burdensome on mariners if they occurred on the weekends. While the contractor expects to only need one 48-hour closure, a second 48-hour closure is scheduled in case of inclement weather or other unforeseen situations which may keep the contractor from working during the weekend of October 10–12. If the work necessitating the 48-hour closure is accomplished during the weekend of October 10–12, 1998, the bridge will be able to open on signal on the weekend of October 17–19, 1998. Local Notice to Mariners and Broadcast Notice to Mariners will provide information on work progress and bridge openings for the weekends of October 10–12, 1998 and October 17–19, 1998.

In the event of an approaching tropical storm or hurricane, work on the bridge will be discontinued and the draw will return to normal operation.

The Coast Guard is, therefore, withdrawing the temporary rule published on September 8, 1998, [CGD08–98–052] and replacing it with this new temporary operating schedule which is less burdensome to navigation.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking for this rule has not been published, and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rule making procedures would have been impracticable. There was not sufficient time to publish proposed rules in advance of implementing the change to the bridge operating procedures or to provide for a delayed effective date.

#### Background and Purpose

The bridge has a vertical clearance of 40 feet above mean high water in the closed-to-navigation position. Mean high water elevation is 3 feet above Mean Sea Level (MSL). Navigation on the waterway consists primarily of fishing vessels, some tugs with tows and occasional recreational craft. Presently, the draw opens on signal for the passage of vessels. The contractor has requested the closure of the bridge to allow for the replacement of the electrical and mechanical components of the bridge and for the pulling of electric conduit wiring on the bridge. During portions of this repair work, scaffolding may be placed below the bridge over the navigation channel reducing the approved vertical clearance to less than 40 feet above mean high water. The reduction in the vertical clearance will be approximately 4 feet. Additionally, if a tropical storm or hurricane develops in the Gulf of Mexico, work will be discontinued and the bridge returned to normal operation for the passage of vessel traffic. Alternate routes are available to vessel operators wishing to enter the area. This work is essential for the continued safe operation of the vertical lift span.

#### Regulatory Evaluation

This temporary rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost 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 Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this temporary rule to be so minimal that a full Regulatory Evaluation paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This is because vessels using the waterway will be allowed to transit the waterway outside of the closure times. In a meeting with representatives of those mariners affected by the closure, it was

determined that this schedule will allow the contractor to complete the required repairs to the bridge while minimizing the effects on navigation interests.

#### Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Coast Guard must consider whether this temporary rule will have a significant economic impact on a substantial number of small entities. "Small entities" may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000. The majority of commercial vessels and fishing vessels that normally transit the bridge will still be able to do so beneath the bridge in the closed-to-navigation position. Thus, the Coast Guard expects there to be no significant economic impact on these vessels. The Coast Guard is not aware of any other waterway users who would suffer economic hardship from being unable to transit the waterway during these closure periods. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this temporary rule will not have a significant economic impact on a substantial number of small entities.

#### Collection of Information

This temporary rule contains no collection-of-information requirements under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

#### Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Environment

The Coast Guard considered the environmental impact of this temporary rule and concluded that this action is categorically excluded from further environmental documentation under current Coast Guard CE #32(e), in accordance with Section 2.B.2 and Figure 2–1 of the National Environmental Protection Act Implementing Procedures, COMDTINST M16475.1C. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under ADDRESSES.

#### List of Subjects in 33 CFR Part 117

Bridges.

**Temporary Regulations**

For the reasons set out in the preamble, the Coast Guard is temporarily amending part 117 Title 33 Code of Federal Regulations as follows:

**PART 117—DRAWBRIDGE OPERATION REGULATIONS**

1. The authority citation for part 117 continues to read as follows:

**Authority:** 33 U.S.C. 499; 49 CFR 1.46; and 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. Effective 8 a.m. on October 5, 1998, through 7 p.m. on November 5, 1998, § 117.465 is amended by adding paragraph (g) to read as follows:

**§ 117.465 Lafourche Bayou.**

\* \* \* \* \*

(g) The draw of the SR 1 bridge, mile 13.3, at Leeville, shall open on signal, except as follows:

(1) From October 5, 1998, until November 5, 1998, the draw need not open for the passage of vessels from 8 a.m. until noon and from 1 p.m. until 6 p.m. on Mondays and from 7 a.m. until 7 p.m. on Tuesdays, Wednesdays, and Thursdays.

(2) The draw need not open for the passage of vessels from 7 a.m. on Saturday, October 10, 1998, until 7 a.m. on Monday, October 12, 1998, and from 7 a.m. on Saturday, October 17, 1998, until 7 a.m. on Monday, October 19, 1998.

(3) In the event of an approaching tropical storm or hurricane, work on the bridge will be discontinued and the draw will return to normal operation.

Dated: September 17, 1998.

**A.L. Gerfin, Jr.,**

*Captain, U.S. Coast Guard, Commander, 8th Coast Guard Dist. Acting.*

[FR Doc. 98-25669 Filed 9-24-98; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-300598A; FRL-6029-1]

RIN 2070-AB78

**Glutamic Acid; Technical Amendment and Correction of Pesticide Tolerance Exemption**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; technical amendment and correction.

**SUMMARY:** EPA is issuing a technical amendment to a final rule and is

correcting the preamble to the final rule that established an exemption from the requirement of a tolerance for residues of the biochemical glutamic acid in or on all food commodities, when applied as a plant growth and crop yield enhancer in accordance with good agricultural practices. This exemption was requested by Auxein Corporation. **DATES:** This technical amendment is effective September 25, 1998.

**FOR FURTHER INFORMATION CONTACT:** By mail: Edward Allen, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: 5th Floor CS #1, 2800 Crystal Drive, Arlington, VA 22202, Telephone No. (703) 308-8699, e-mail: allen.edward@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the January 7, 1998 issue of the **Federal Register** (63 FR 679)(FRL-5764-4) the Office of Pesticide Programs issued a final rule exempting the biochemical glutamic acid from the requirement of a tolerance on all raw agricultural commodities when used as a plant growth enhancer in accordance with good agricultural practices. This tolerance was requested by Auxein Corporation, P.O. Box 27519, 3125 Sovereign Drive, Suite B, Lansing, MI 48911. Throughout the preamble to the final rule and in the codified text (40 CFR 180.1187), reference was made to "glutamic acid." Auxien Corporation has brought to the Agency's attention that the requested tolerance was for residues of "L-glutamic acid" rather than "glutamic acid." This technical amendment corrects the preamble and the codified text in the January 7, 1998 final rule. Therefore, in the preamble to FR Doc. 98-359, published at 63 FR 679, January 7, 1998, reference to "glutamic acid" should be changed to refer to "L-glutamic acid." The amendment to 40 CFR 180.1187 is set forth below.

**I. Regulatory Assessment Requirements****A. Certain Acts and Executive Orders**

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork

Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

**B. Executive Order 12875**

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

**C. Executive Order 13084**

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes