

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