

organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

—The ANADA is approved as a generic copy of Fort Dodge Laboratories' NADA 127-892, Amiglyde-V® (amikacin sulfate solution). ANADA 200-181 is approved as of March 18, 1997, and the regulations are amended in 21 CFR 529.50 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 529

—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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

—1. The authority citation for 21 CFR part 529 continues to read as follows:

—**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.50 [Amended]

—2. Section 529.50 *Amikacin sulfate intrauterine solution* is amended in paragraph (b) by adding the phrase “and 059130” after “000856”.

Dated: April 7, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97-11080 Filed 4-29-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD08-97-008]

RIN 2115-AE84

Amendment to Regulated Navigation Area Regulations; Lower Mississippi River

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: On March 18, 1997, the Coast Guard established a temporary regulated navigation area affecting the operation of downbound tows in the Lower Mississippi River from mile 437 at Vicksburg, MS to mile 88 above Head of Passes. These regulations were subsequently amended on March 21, March 28, April 4 and April 15. The amendments added additional operating requirements for vessels of 1600 gross tons or greater, increased the operating limitations on tank barges and ships carrying hazardous chemicals and gasses, and extended the RNA to the boundary of the territorial sea at the approaches to Southwest Pass. On April 15, in response to moderating river conditions, the regulations were relaxed to permit tows of up to 30 barges to operate when being pushed by tow boats of 9,000 brake horsepower or greater.

The threat posed by high water and currents on the Lower Mississippi River has continued to abate. The water level at the Baton Rouge Gauge crested on March 26 at 43.8 feet. By April 14, it had fallen to 39.6 feet and has continued to fall. It is projected to reach 37.0 feet on April 20, 1997. Similarly, the river current at the Baton Rouge Gauge had fallen from a high of approximately 9 miles per hour on March 26 to 7.3 miles per hour as of 14 April. On April 20, it is projected to be 6 miles per hour. After consultation with marine industry groups, state government agencies, and river pilots organizations, the district commander has decided to further amend the regulations. This amendment will permit the tow boat and barge limitations and chemical and gas ship operating restrictions to expire as scheduled at 12 p.m. on April 20, 1997, while maintaining the regulations affecting self-propelled vessels of 1,600 gross tons or greater.

The regulated navigation area is needed to protect vessels, bridges, shore-side facilities and the public from a safety hazard created by deep draft

vessel operations along the Lower Mississippi River during the periods of high water in late spring and early summer. Self-propelled vessels of 1600 or more gross tons are prohibited from operating in this area unless they are in compliance with this regulation.

DATES: This amended regulation is effective at 12 p.m. on April 20, 1997 and terminates at 12 p.m. on July 1, 1997.

FOR FURTHER INFORMATION CONTACT: CDR Harvey R. Dexter, Marine Safety Division, USCG Eighth District at New Orleans, LA (504) 589-6271.

SUPPLEMENTARY INFORMATION:

Background and Purpose

On March 18, 1997 (62 FR 14637, March 27, 1997), the Coast Guard established a temporary regulated navigation area affecting the operation of downbound tows in the Lower Mississippi River from mile 437 at Vicksburg, MS to mile 88 above Head of Passes. On March 21, 1997 (62 FR 15398, April 1, 1997), the Coast Guard amended the temporary regulated navigation area by extending the southern limit of the regulated navigation area to the boundary of the territorial sea at the approaches to Southwest Pass and included operating requirements affecting the operation of self-propelled vessels of 1600 gross tons or greater. Increasing high water conditions caused the Coast Guard to amend this regulation for a second time on March 28, 1997 (62 FR 16081, April 4, 1997) to establish additional safety measures applicable to U.S. flagged and foreign-flagged vessels authorized to carry cargoes listed under Title 46, Code of Federal Regulations Part 151 (chemical barges) and Parts 153-154 (chemical and gas ships).

Although Lower Mississippi River floodwater levels had receded somewhat by April 4, river current remained at a record high level at that time. The loss of control of a tow as it entered the Mississippi River from the Port Allen lock and several near-misses involving tows longer than 600 feet exiting locks into the Mississippi River evidenced the need to further limit the length of tows. It was determined that, by limiting the maximum length of tows during the critical period when they were entering or exiting locks along the Mississippi River to or from the relatively still water of a lock forebay, towboats would be able to exercise greater control of the tow during that critical period. Therefore, on April 4, 1997 (62 FR 17704, April 11, 1997) the district commander amended this regulation for the third time to prohibit

tows in excess of 600 feet from entering or exiting lock forebays. This amendment also clarified the horsepower restrictions in the earlier regulation to make it clear that the horsepower rating of escort tugs cannot be counted in establishing the number of barges that may be included in a tow. The Coast Guard also extended the effective date of the regulation to April 20, 1997, because the high water conditions were expected to last longer than originally contemplated.

The threat posed by high water and currents on the Lower Mississippi River has continued to abate. The water level at the Baton Rouge Gauge crested on March 26 at 43.8 feet. By April 14, it had fallen to 39.6 feet, and has continued to fall. It is projected to reach 37.0 feet on April 20, 1997. The river current at the Baton Rouge Gauge fell from a high of approximately 9 miles per hour on March 26 to 7.3 miles per hour on April 14. On April 20, it is projected to be 6 miles per hour. Several downbound test runs with varying tow and tow boat configurations have established that river conditions are much safer for large tow configurations than when this RNA was established.

Although the district commander has determined that water levels and current speeds in the lower Mississippi River have returned to a level that will permit the relaxation of some operating restrictions on tow boats and tows, it is anticipated that spring rains and unusually high water runoff from snow melt in the upper reaches of the Mississippi River drainage will maintain higher than normal river and current levels in the Lower Mississippi River for the foreseeable future. This amendment does not affect the expiration on April 20th of rules regulating barge number and horsepower requirements and chemical and tank vessel operating restrictions. However, the Captain of the Port, Marine Safety Office New Orleans has established a vessel control safety zone in the vicinity of Wilkinson Point from mile 225 to mile 238 on the Lower Mississippi River to address navigational safety concerns unique to that area. The requirements of this safety zone remain in effect until changed by the Captain of the Port. Any such changes will be included in a Marine Information Broadcast and other communications to the industry.

Based on problems experienced by deep draft vessels operating on the Lower Mississippi River in late spring and early summer during periods of unusually high water and current, as is anticipated to be the case this year, the district commander has deemed it

necessary to continue the requirements of the RNA for vessels of 1,600 tons or greater until July 1, 1997. In most years, river and current levels have returned to normal after July 1.

During 1995 and 1996 a total of 86 self-propelled vessels of 1,600 gross tons or greater experienced casualties involving loss of power, loss of steering or engine irregularities during the months of April through June. Serious consequences may result from such casualties, especially during high water periods. Engine failure was the probable cause of the recent M/V BRIGHT FIELD allision that caused millions of dollars of property damage and posed grave threats of death and personal injury to persons in the vicinity of the allision.

The regulations left in place by the district commander are intended to enhance the safety of navigation on the river and protect shoreside facilities by causing masters and engineers to take measures that will minimize the risk of steering casualties and engine failure and irregularities. They also place the ship in a manning status and operating condition that will allow the vessel to take prompt and appropriate emergency action should a casualty occur thereby reducing the likelihood of a cascading series of allisions and collisions following a casualty. Communications from river pilots operating within the RNA have established the necessity and viability of these regulations and the necessity for their continuation during a period of traditionally high casualty rates. As a result of the operating restrictions, pilots have seen improvements in vessels' readiness to respond to steering casualties and main propulsion irregularities and failures.

This rule requires that all self-propelled vessels to which 33 Code of Federal Regulations § 164 applies, shall comply with the following:

(a) Masters shall review the requirements of 33 CFR 164.25 pertaining to "Tests Before Entering or Getting Underway."

(b) The engine room shall be manned at all times when underway in the RNA.

(c) Prior to entering the RNA or getting underway within the RNA, the master of each vessel shall report to the ship's agent that the regulations at 33 CFR 164.25 have been reviewed, are understood, and the vessel is in compliance with the regulation.

(d) As part of the master's report, the chief engineer shall also certify that the following additional operating conditions will be satisfied so long as the vessel is underway within the RNA:

(1) If the vessel has an automated main propulsion plant, it will be operated in manual mode and will be

prepared to answer maneuvering commands immediately.

2. The vessel shall immediately provide maximum ahead or astern power when so ordered by the bridge.

3. The main propulsion plant shall, in all respects, be ready for operations in the RNA including the main propulsion air start systems, fuel systems, lube oil systems, cooling systems, and automation systems.

4. The master shall also certify that the gyrocompass is properly operating and calibrated.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of notice of proposed rulemaking and delay of effective date would be contrary to public interest because immediate action is necessary to ensure self-propelled vessels are capable of operating safely on the river and prevent allisions with bridges and shore-side structures, and colliding with other vessels, causing danger to the public.

Regulatory Evaluation

This 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. It has not been reviewed by the Office of Management and Budget 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 rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule, if adopted, 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. Small entities in this case would not include a significant number of companies operating vessels of 1600 gross tons or greater due to the nature and cost of operating vessels of this size. The operating and manning requirements

established by this regulation are those of a prudent mariner and impose little or no additional financial burden on the vessel. Similarly, vessels routinely communicate with their agents prior to getting underway or entering port. Therefore, the costs associated with the requirement to include a certification that the vessel is in compliance with 33 CFR 164.25 and certain other safety related requirements are insignificant. This rule is deemed to not have a substantial economic impact.

Collection of Information

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

Federalism Implications

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this proposal and concluded that under paragraph 2.B.2(g)(5) of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (waters), Reporting and recordkeeping requirements, safety measures, Waterways.

Final Regulations

For the reasons set out in the preamble the Coast Guard amends 33 CFR Part 165 as follows:

PART 165 [AMENDED]

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; 46 CFR 1.46.

2. In § 165.T08-001, paragraphs (b)(1), (b)(2), (b)(3), (b)(4) are revised; (b)(5), (b)(6), (b)(7), (b)(8), (b)(9), (b)(10), (b)(11), (b)(12), (b)(13), (b)(14), (b)(15) are removed; and paragraph (c) is revised to read as follows:

§ 165.T08-001. Regulated Navigation Area, Lower Mississippi River.

* * * * *

(b) * * *

(1) In accordance with general regulations in § 165.11 of this part, no self-propelled vessels of 1600 gross tons may operate within the Regulated Navigation Area (RNA) contrary to this regulation.

(2) All self-propelled vessels to which the regulations at 33 CFR part 164 apply, shall comply with the following:

(i) Masters shall review the requirements of 33 CFR 164.25 pertaining to "Tests Before Entering or Getting Underway."

(ii) The engine room shall be manned at all times while underway in the RNA

(iii) Prior to entering or getting underway in the RNA, the master of each vessel shall report to the ship's agent that 33 CFR part 164 has been reviewed, the requirements are understood, and his vessel is in compliance with the regulation.

(iv) The master shall also report that the chief engineer has certified that the following additional operating conditions will be satisfied so long as the vessel is underway within the RNA:

(A) If the vessel has an automated main propulsion plant, it shall be operated in manual mode and will be prepared to answer maneuvering commands immediately.

(B) The vessel shall immediately provide maximum ahead or astern power when so ordered by the bridge.

(C) The main propulsion plant shall in all respects be ready for operations in the regulated navigation area including the main propulsion air start systems, fuel systems, lube oil systems, cooling systems, and automation systems.

(v) The master shall also certify that the gyrocompass is properly operating and calibrated.

(3) For vessels subject to this regulation, Commander, Eighth Coast Guard District urges that main propulsion standby systems be placed on-line or be ready to be placed on-line immediately.

(4) The Captain of the Port will notify the public of changes in the status of this zone by Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 22 (157.1 MHz).

(c) Effective dates: This section is effective at 12 p.m. on April 20, 1997 and terminates at 12 p.m. on July 1, 1997.

Dated: April 19, 1997.

Timothy W. Josiah,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 97-11209 Filed 4-29-97; 8:45 am]

BILLING CODE 4410-14-M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket Nos. RM 89-2, RM 89-2A]

Cable Compulsory License: Merger of Cable Systems and Individual Pricing of Broadcast Signals

AGENCY: Copyright Office, Library of Congress.

ACTION: Final rule and termination of proceeding.

SUMMARY: The Copyright Office is amending its rules to permit cable systems to calculate the 3.75% rate fee for distant signals on a "partially permitted signal" basis where applicable. In addition, due to a Congressional request that the Office consider revision of the cable compulsory license, among other things, the Office is terminating Docket Nos. RM 89-2 and 89-2A until further notice.

EFFECTIVE DATE: May 30, 1997.

FOR ADDITIONAL INFORMATION CONTACT: Nanette Petruzzelli, Acting General Counsel, or William Roberts, Senior Attorney for Compulsory Licenses, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, DC 20024. Telephone (202) 707-8380. Telefax: (202) 707-8366.

SUPPLEMENTARY INFORMATION:

I. Background

Section 111 of the Copyright Act, 17 U.S.C. 111, establishes a compulsory license which authorizes cable systems to make secondary transmissions of copyrighted works embodied in broadcast signals provided that they pay a royalty calculated on a formula set out in sec. 111,¹ and meet all other conditions contained in sec. 111.

On September 18, 1989, the Copyright Office published a Notice of Inquiry (NOI) in Docket No. RM 89-2 asking the public to comment on how mergers and acquisitions of cable systems that result in contiguous systems under common ownership or control should affect the calculation of royalties under 17 U.S.C. 111. 54 FR 38930 (Sept. 18, 1989).

Specifically, the NOI asked for comments on the following provision of 17 U.S.C. 111(f),

(f) for purposes of determining the royalty fee under subsection (d)(1), two or more cable

¹ The formula is set out in 17 U.S.C. 111, but the rates and the gross receipts thresholds were amended by the former Copyright Royalty Tribunal and could be further amended by a future Copyright Arbitration Royalty Panel. 37 CFR 251.2; 37 CFR 256.2.