

the Associate Commissioner for Disability Determinations or his or her delegate to be deficient, the Associate Commissioner or his or her delegate will take appropriate action to assure that the deficiency is corrected before a reconsidered determination is issued. The action taken by the Associate Commissioner or his or her delegate will take one of two forms:

(1) The Associate Commissioner or his or her delegate may return the case file either to the component responsible for preparing the case for hearing or to the disability hearing officer, for appropriate further action; or

(2) The Associate Commissioner or his or her delegate may issue a written reconsidered determination which corrects the deficiency.

(c) *Further action on your case if it is sent back by the Associate Commissioner for Disability Determinations or his or her delegate either to the component that prepared your case for hearing or to the disability hearing officer.* If the Associate Commissioner for Disability Determinations or his or her delegate sends your case back either to the component responsible for preparing the case for hearing or to the disability hearing officer for appropriate further action, as provided in paragraph (b)(1) of this section, any additional proceedings in your case will be governed by the disability hearing procedures described in § 416.1416(f) or if your case is returned to the disability hearing officer and an unfavorable determination is indicated, a supplementary hearing may be scheduled for you before a reconsidered determination is reached in your case.

(d) *Opportunity to comment before the Associate Commissioner for Disability Determinations or his or her delegate issues a reconsidered determination that is unfavorable to you.* If the Associate Commissioner for Disability Determinations or his or her delegate proposes to issue a reconsidered determination as described in paragraph (b)(2) of this section, and that reconsidered determination is unfavorable to you, he or she will send you a copy of the proposed reconsidered determination with an explanation of the reasons for it, and will give you an opportunity to submit written comments before it is issued. At your request, you will also be given an opportunity to inspect the pertinent materials in your case file, including the reconsidered determination prepared by the disability hearing officer, before submitting your comments. You will be given 10 days from the date you receive the Associate Commissioner's notice of

proposed action to submit your written comments, unless additional time is necessary to provide access to the pertinent file materials or there is good cause for providing more time, as illustrated by the examples in § 416.1411(b). The Associate Commissioner or his or her delegate will consider your comments before taking any further action on your case.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003P-0564]

Microbiology Devices; Reclassification of Hepatitis A Virus Serological Assays; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 9, 2006 (71 FR 6677). That document reclassified hepatitis A virus (HAV) serological assays from class III (premarket approval) into class II (special controls). That document inadvertently published with an error. This document corrects the error.

DATES: This rule is effective March 13, 2006.

FOR FURTHER INFORMATION CONTACT:

Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-0496.

SUPPLEMENTARY INFORMATION: In FR Doc. 06-1206, appearing on page 6677 in the **Federal Register** of Thursday, February 9, 2006, the following correction is made:

1. On page 6679, beginning in the first column, under section "VI. Analysis of Impacts," the second paragraph is corrected to read:

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of HAV serological assays from class III into class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to these devices, the agency certifies that the final rule will not

have a significant economic impact on a substantial number of small entities.

Dated: February 21, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05-05-079]

RIN 1625-AA09

Drawbridge Operation Regulations; New Jersey Intracoastal Waterway, Manasquan River

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the operating regulations that govern the operation of the Route 35 Bridge, at New Jersey Intracoastal Waterway (NJICW) mile 1.1, across Manasquan River, at Brielle, New Jersey. The bridge will be closed to navigation on three four-month closure periods from 8 a.m. November 1, 2006 until 5 p.m. March 1, 2007; from 8 a.m. on November 1, 2007 until 5 p.m. March 1, 2008; and from 8 a.m. on November 1, 2008 until 5 p.m. March 1, 2009. Extensive structural, mechanical, and electrical repairs and improvements necessitate these closures.

DATES: This temporary final rule is effective from April 17, 2006.

ADDRESSES: The 5th Coast Guard District maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket are part of docket CGD05-05-079 and are available for inspection or copying at Commander (obr), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23703-5004, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Gary Heyer, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398-6629.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On July 20, 2005, we published a notice of proposed rule making (NPRM)

entitled "Drawbridge Operation Regulations; New Jersey Intracoastal Waterway, Manasquan River" in the **Federal Register** [FR Doc. 05-14322]. We received four (4) comments on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The New Jersey Department of Transportation (NJDOT) owns and operates the Route 35 Bridge, at NJICW mile 1.1, across Manasquan River, at Brielle, New Jersey. The current operating regulations set out in 33 CFR 117.733(b) requires the drawbridge to open on signal except as follows: from May 15 through September 30, on Saturdays, Sundays and Federal holidays, from 8 a.m. to 10 p.m., the draw need only open 15 minutes before the hour and 15 minutes after the hour; on Mondays to Thursdays from 4 p.m. to 7 p.m., and on Fridays, except Federal holidays from 12 p.m. to 7 p.m., the draw need only open 15 minutes before the hour and 15 minutes after hour; and year-round from 11 p.m. to 8 a.m., the draw need only open if at least four hours notice is given.

Parsons Brinkerhoff, a design consultant, on behalf of NJDOT requested a temporary change to the existing regulations for the Route 35 Bridge to facilitate necessary repairs. The repairs, which consist of extensive structural rehabilitation, mechanical, and electrical repairs and improvements, necessitate this closure. To facilitate repairs, the bascule span must be closed to vessel traffic on three four-month closure periods from 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2007; from 8 a.m. on November 1, 2007 until 5 p.m. March 1, 2008; and from 8 a.m. on November 1, 2008 until 5 p.m. March 1, 2009.

The Coast Guard has reviewed the bridge data provided by NJDOT. The data, from years 2003 to 2005, shows a substantial decrease in the number of bridge openings and vessel traffic transiting the area between November and March. Based on the data provided, these closure dates will have minimal impact on vessel traffic.

Discussion of Comments and Changes

The Coast Guard received four (4) comments on the NPRM [FR Doc. 05-14322] governing the Route 35 Bridge over the Manasquan River, at NJICW mile 1.1, at Brielle, New Jersey, set out in 33 CFR 117.733(b). The comments were from local vessel owners and supportive of the temporary change. The Coast Guard will temporarily suspend 33 CFR 117.733(b) and insert this new specific regulation at 33 CFR 117.733(l).

Paragraph (l) would allow the draw to be closed to vessel traffic during the rehabilitation project on three four-month closure periods from 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2007; from 8 a.m. on November 1, 2007 until 5 p.m. March 1, 2008; and from 8 a.m. on November 1, 2008 until 5 p.m. March 1, 2009.

Discussion of Rule

The Coast Guard made a drafting error in the NPRM [FR Doc. 05-14322]. However, this error does not affect the intent of this temporary final rule, so a supplemental NPRM will not be published.

The text of the rule will be revised as described in the next paragraph.

From 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2009; in § 117.733, suspend paragraph (b) and add a new paragraph (l) to read as follows:

(l) The draw of the Route 35 Bridge, mile 1.1 across Manasquan River at Brielle, shall open on signal except as follows:

(1) From May 15 through September 30:

(i) On Saturdays, Sundays and Federal holidays, from 8 a.m. to 10 p.m., the draw need only open 15 minutes before the hour and 15 minutes after the hour.

(ii) On Mondays to Thursdays from 4 p.m. to 7 p.m. and on Fridays, except Federal holidays from 12 p.m. to 7 p.m., the draw need only open 15 minutes before the hour and 15 minutes after the hours.

(2) Year-round, unless provided by (1)(3), from 11 p.m. to 8 a.m., the draw need only open if at least four hours notice is given.

(3) From 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2007; from 8 a.m. on November 1, 2007 until 5 p.m. March 1, 2008; and from 8 a.m. on November 1, 2008 until 5 p.m. March 1, 2009, the Route 35 Bridge, mile 1.1, at Brielle may remain in the closed position to navigation.

Regulatory Evaluation

This temporary final 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).

We expect the economic impact of this temporary final rule to be so

minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. We reached this conclusion based on the historical data, and on the fact that the closure periods support minimal impact due to the reduced number of vessels requiring transit through the bridge.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this temporary final 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 temporary final rule would not have a significant economic impact on a substantial number of small entities. The off-season closure dates for the bridge are designed to minimize the number of small entities affected.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, (757) 398-6222. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

A temporary final 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 temporary final 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 temporary final 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 would not affect 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 temporary final 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 temporary final rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This temporary final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 temporary final rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this temporary final rule under Commandant Instruction M16475.lD, 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 temporary final rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation because it has been determined that the promulgation of operating regulations for drawbridges are categorically excluded.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

- For the reasons discussed in the preamble, the Coast Guard will amend 33 CFR part 117 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; 33 CFR 1.05–1(g); Department of Homeland Security Delegation No. 0170.1; section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

- 2. From 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2009; in § 117.733, suspend paragraph (b) and add a new paragraph (l) to read as follows:

§ 117.733 New Jersey Intracoastal Waterway.

* * * * *

(l) The draw of the Route 35 Bridge, mile 1.1 across Manasquan River at Brielle, shall open on signal except as follows:

(1) From May 15 through September 30:

(i) On Saturdays, Sundays and Federal holidays, from 8 a.m. to 10 p.m., the draw need only open 15 minutes before the hour and 15 minutes after the hour.

(ii) On Mondays to Thursdays from 4 p.m. to 7 p.m. and on Fridays, except Federal holidays from 12 p.m. to 7 p.m., the draw need only open 15 minutes before the hour and 15 minutes after the hours.

(2) Year-round, unless otherwise provided by paragraph (l)(3) of this section, from 11 p.m. to 8 a.m., the draw need only open if at least four hours notice is given.

(3) From 8 a.m. on November 1, 2006 until 5 p.m. March 1, 2007; from 8 a.m. on November 1, 2007 until 5 p.m. March 1, 2008; and from 8 a.m. on November 1, 2008 until 5 p.m. March 1, 2009, the Route 35 Bridge, mile 1.1, at Brielle may remain in the closed position to navigation.

Dated: February 17, 2006.

Larry L. Hereth,

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

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