

control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification and the special control guidance document for cyclosporine and tacrolimus test systems by adding new §§ 862.1235 and 862.1678. For the convenience of the reader, FDA is also adding a new § 862.1(d) to inform the reader where to find guidance documents referenced in part 862.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96-354) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of cyclosporine and tacrolimus assays from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Furthermore, the special controls guidance document does not impose any new burdens on manufacturers; it advises manufacturers about ways to comply with the special controls that allow the agency to down classify these devices. By eliminating the need for premarket approval

applications, reclassification will reduce regulatory costs with respect to these devices, impose no significant economic impact on any small entities, and may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 862.1 is amended by adding new paragraph (d) to read as follows:

§ 862.1 Scope.

* * * * *

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 862.1235 is added to subpart B to read as follows:

§ 862.1235 Cyclosporine test system.

(a) *Identification.* A cyclosporine test system is a device intended to quantitatively determine cyclosporine concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for cyclosporine.

(b) *Classification.* Class II (special controls). The special control is "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA." See § 862.1(d) for the availability of this guidance document.

4. Section 862.1678 is added to subpart B to read as follows:

§ 862.1678 Tacrolimus test system.

(a) *Identification.* A tacrolimus test system is a device intended to quantitatively determine tacrolimus concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for tacrolimus.

(b) *Classification.* Class II (special controls). The special control is "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA." See § 862.1(d) for the availability of this guidance document.

Dated: August 19, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02-23508 Filed 9-13-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-02-108]

RIN 2115-AE47

Drawbridge Operation Regulations: Passaic River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the Route 7

(Rutgers Street) Bridge, at mile 8.9, across the Passaic River at Belleville, New Jersey. This rule allows the bridge to remain in the closed position from September 13, 2002 through October 15, 2002. This action is necessary to facilitate structural work at the bridge.

DATES: This temporary final rule is effective from September 13, 2002 through October 15, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket (CGD01-02-108) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 6:30 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Arca, Project Officer, First Coast Guard District, (212) 668-7165.

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 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 Coast Guard believes notice and comment are unnecessary because the only vessel operator upstream from the bridge can pass under the bridge without a bridge opening. In view of the historic absence of bridge opening requests and the demonstrated need to complete structural work at the bridge, any delay encountered in this regulation's effective date would be unnecessary and contrary to the public interest.

Background

The Route 7 Bridge has been replaced with a new Route 7 Bridge. The final phase of the new bridge construction involves the installation of the roadway deck, during which, the bridge will not be able to open for vessel traffic.

The bridge owner, New Jersey Department of Transportation, requested a change to the temporary regulation to facilitate the remaining construction. On June 26, 2002, we published a temporary final rule (67 FR 42997) for the Route 7 (Rutgers Street) Bridge. That temporary final rule allowed the bridge to remain in the closed position from June 15, 2002 through September 3, 2002, to facilitate the installation of the roadway deck.

Subsequent to publication of the above temporary final rule, the Coast Guard was notified by the owner of the bridge that the June 15, 2002, start date for the repair work and bridge closure would be postponed because of a delay in the delivery of materials required for the project.

The commencement of repair work and the bridge closure did not actually begin until July 24, 2002. As a result of the above delay in the commencement of the bridge construction, the end date for the temporary final rule must be extended.

The Coast Guard believes this temporary final rule is reasonable because no vessel traffic will be precluded from transiting this bridge as a result of the bridge closure. Presently there is only one vessel operator upstream from the bridge and that vessel can pass under the bridge without a bridge opening.

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 Transportation (DOT) (44 FR 11040; February 26, 1979).

This conclusion is based on the fact that no known vessel traffic will be prevented from transiting the bridge as a result of this closure.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we 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 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 conclusion is based on the fact that no known vessels will be prevented from transiting the bridge as a result of this bridge closure.

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 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 concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that under figure 2-1, paragraph (32)(e), of Commandant Instruction M16475.1d, this rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the environment. 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.

Regulations

For the reasons set out in the preamble, the Coast Guard amends 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; 49 CFR 1.46; 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. From September 13, 2002 through October 15, 2002, section 117.739 is temporarily amended by suspending paragraph (k) and adding a new paragraph (q) to read as follows:

§ 117.739 Passaic River.

* * * * *

(q) The draw of the Route 7 (Rutgers Street) Bridge, mile 8.9, need not open for the passage of vessel traffic from September 13, 2002 through October 15, 2002.

Dated: September 9, 2002.

V.S. Crea,

*Rear Admiral, Coast Guard, Commander,
First Coast Guard District.*

[FR Doc. 02-23479 Filed 9-13-02; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Pittsburgh-02-019]

RIN 2115-AA97

Security Zone; Ohio River Mile 119.0 to 119.8, Natrium, WV

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone encompassing all water extending 200 feet from the water's edge of the left descending bank on the Ohio River, beginning from mile marker 119.0 and ending at mile marker 119.8. This security zone is necessary to protect Pittsburgh Plate Glass Industries (PPG), persons, and vessels from subversive or terrorist acts. Entry of persons or vessels into this security zone is prohibited unless authorized by the Coast Guard Captain of the Port Pittsburgh or designated representative.

DATES: This rule is effective from 3 p.m. on August 30, 2002 to 3 p.m. on February 15, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket [COTP Pittsburgh-02-019] and are available for inspection or copying at Marine Safety Office Pittsburgh, Suite 1150 Kossman Bldg., 100 Forbes Ave., Pittsburgh, PA between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Michael Marsula, Marine Safety Office Pittsburgh at (412) 644-5808 x114.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this rule. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

National security and intelligence officials warn that future terrorist attacks against United States interests

are likely. Current advisories of terrorist threats, a history of violence directed towards this facility, and the nature of material handled at Pittsburgh Plate Glass Industries (PPG) make this rulemaking necessary for the protection of national security interests. Any delay in making this regulation effective would be contrary to the public interest because action is necessary to protect against the possible loss of life, injury, or damage to property.

The Coast Guard will, during the effective period of this temporary final rule, complete notice and comment rulemaking for a proposed permanent regulation.

Background and Purpose

A temporary security zone for this area expired on June 15, 2002 (67 FR 9589, March 4, 2002). We received no comments or objections regarding this zone. Advisories regarding continued threats of terrorism have revealed the need for another security zone to protect PPG, persons, and vessels from subversive or terrorist acts. To enhance security the Captain of the Port is establishing a temporary security zone.

This security zone includes all water extending 200 feet from the water's edge of the left descending bank on the Ohio River beginning from mile marker 119.0 and ending at mile marker 119.8. All persons and vessels are prohibited from entering the zone without the permission of the Captain of the Port Pittsburgh or designated representative.

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 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 Transportation (DOT) (44 FR 11040, February 26, 1979).

The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This rule does not obstruct the regular flow of vessel traffic and will allow vessel traffic to pass safely around the security zone. Vessels may be permitted to enter the security zone on a case-by-case basis.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this rule would have a significant economic impact on a