

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) remove the entry for “Jazz Pharmaceuticals, Inc.” and alphabetically add a new entry for “Paladin Labs, Inc.”; and in the table in paragraph (c)(2) remove the entry for “068727” and numerically add a new entry for “046129” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904 * * *	* * 046129 * *

(2) * * *

Drug labeler code	Firm name and address
* * 046129 * *	* * * Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904 * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1004 [Amended]

■ 4. In paragraph (b) of § 522.1004, remove “068727” and add in its place “046129”.

Dated: June 1, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-13126 Filed 6-4-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2009-0385]

RIN 1625-AA09

Drawbridge Operation Regulation; Sturgeon Bay Ship Canal, Sturgeon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard proposes to temporarily revise the operating regulations for the Maple-Oregon Bridge at Mile 4.17 over the Sturgeon Bay Ship Canal in Sturgeon Bay, WI. This action was requested by the Wisconsin Department of Transportation (Wisconsin DOT) to facilitate vehicular traffic in downtown Sturgeon Bay during the rehabilitation of the Michigan Street Bridge at Mile 4.30 over the Sturgeon Bay Ship Canal. This final rule is expected to reflect the need for bridge openings for the Maple-Oregon Bridge during the Michigan Street Bridge rehabilitation and still provide for the reasonable needs of navigation.

DATES: This temporary final rule is effective from 6 a.m. on June 1, 2009 to 6 p.m. on November 15, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket USCG-2009-0385 and are available by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2009-0385 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Blair Stanifer, Bridge Management Specialist, Coast Guard Ninth District; telephone 216-902-6086, e-mail: William.B.Stanifer@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the request to revise the operating schedule for this temporary final rule included extensive preliminary coordination with known affected marine entities, Wisconsin DOT, and the City of Sturgeon Bay, WI, and resulted in a temporary drawbridge schedule that would not significantly impact either vehicular traffic or known navigation.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. As noted above the Coast Guard has conducted extensive preliminary coordination with known affected marine entities, the Wisconsin DOT and the City of Sturgeon Bay, WI and determined that the impact on navigation will be minimal as the bridge will continue to open on demand for commercial vessels and public vessels and on the hour for recreational vessels from March 15 through December 31, and from January 1 through March 14, for any vessel provided at least notice is given at least 12 hours advance. This is the same schedule under which the Michigan Street Bridge currently operates under 33 CFR 117.1101. During renovation the Michigan Street Bridge will remain in the open position and vehicular traffic is expected to use the Maple-Oregon Bridge as an alternate route. Repeated openings would likely cause significant congestion on the vehicular approaches to the bridge. Hourly openings will allow vehicular traffic to plan accordingly and will minimally affect recreational vessels.

Background and Purpose

Wisconsin DOT requested a temporary change to the operating schedule of the Maple-Oregon Bridge at Mile 4.17 over the Sturgeon Bay Ship Canal to facilitate the rehabilitation of the Michigan Street Bridge. The Maple-Oregon Double-Leaf Bascule Bridge navigation span provides for a design clearance of 25 feet above Mean Low

Water in the closed to navigation position. The waterway carries commercial, recreational and public vessel traffic. The bridge is normally required to open on signal for vessels year-round under the general provisions of 33 CFR 117.5. In order to perform the rehabilitation to the Michigan Street Bridge with a minimum of disruptions, Wisconsin DOT has requested that the Maple-Oregon Bridge be required to open for recreational vessels only on the hour, 24 hours a day, seven days a week, between March 15 and December 31. The Maple-Oregon Bridge will continue to open on demand for commercial and public vessels during this period. Between January 1 and March 14, the Maple-Oregon Bridge will open if notice is provided at least 12 hours in advance of a vessel's time of intended passage. As the Michigan Street Bridge currently operates under this schedule as outlined in 33 CFR 117.1101, Wisconsin DOT feels that operating the Maple-Oregon Bridge with this schedule will maintain the expectations of the waterway users and vehicular traffic while the Michigan Street Bridge is rehabilitated in the open to navigation position. The request from Wisconsin DOT also included undefined periods of time where the Maple-Oregon Bridge would not be required to open for any vessel as work being performed on the Michigan Street Bridge would necessitate the occasional, short-term closing of the waterway. The dates of these closure periods can not, and have not, been identified due to the nature of the work, but Wisconsin DOT is required to provide those dates to the Coast Guard 10–14 days in advance of anticipated closure periods. The Coast Guard will issue Broadcast and Local Notices to Mariners covering those dates when they have been finalized.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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. This rule is not “significant” under the regulatory policies and procedures of the Department of Homeland Security. The temporary

drawbridge schedule still provides for the passing of vessels throughout the entire proposed work period. The unspecified closure periods, which are necessary for a limited amount of rehabilitation work being performed on the Michigan Street Bridge, will be published as early as possible in the Ninth Coast Guard District Local and/or Broadcast Notice to Mariners prior to the work beginning.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have 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 of 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 rule will affect the following entities, some of which may be small entities: the owners or operators of recreational vessels intending to transit the bridge from 6 a.m. on June 1, 2009 to 6 p.m. on November 15, 2010, and marine facilities that provide services for recreational vessels. However, this action will not have a significant economic impact on a substantial number of small entities for the following reasons. The Maple-Oregon Bridge was designed to pass a substantial amount of waterway users without the need for an opening. Vessels that can safely transit under the bridge may do so at any time. The remaining vessels will still be granted openings once an hour on the hour, twenty-four hours a day. Before the effective period, we will issue maritime advisories widely available to users of the river.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The

Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). 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 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 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 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 would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 0023.1 and Commandant Instruction M16475.1D, 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human

environment. This rule is categorically excluded, under figure 2-1, paragraph (32)(e), of the Instruction.

Under figure 2-1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons discussed 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; 33 CFR 1.05-1; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 6 a.m. on June 1, 2009 to 6 p.m. on November 15, 2010, temporarily add paragraph (c) to § 117.1101 to read as follows:

§ 117.1101 Sturgeon Bay.

* * * * *

(c) The draw of the Maple-Oregon Bridge at Mile 4.17 at Sturgeon Bay, shall operate as follows:

(1) From June 1 through December 31, 2009, and from March 15 through November 15, 2010 the draw need open for recreational vessels only on the hour, 24 hours a day.

(2) Commercial and Public vessels shall be passed at all times.

(3) From January 1 through March 14, 2010, the draw shall open on signal for all vessels if notice is given at least 12 hours in advance of a vessel's intended time of passage.

Dated: May 18, 2009.

D.R. Callahan,

Captain, U.S. Coast Guard, Commander, Ninth Coast Guard District, Acting.

[FR Doc. E9-13103 Filed 6-4-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0120]

RIN 1625-AA00

Safety Zone; Coronado Fourth of July Fireworks; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Diego Bay in support of the Coronado Fourth of July Fireworks. This temporary safety zone is necessary to provide for the safety of crew, spectators, and other users and vessels of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this temporary safety zone unless authorized by the Captain of the Port or his designated representative.

DATES: This rule is effective from 8:45 p.m. to 9:30 p.m. on July 4, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0120 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2009-0120 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Petty Officer Kristen Beer, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619-278-7262, e-mail Kristen.A.Beer@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 27, 2009, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Coronado Fourth of July Fireworks; San Diego Bay, San Diego, CA in the **Federal Register** (74 FR 19034). We received no comments on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

Coronado 4th of July, Inc. is sponsoring the Coronado Fourth of July Fireworks, which will include a fireworks presentation originating from a barge located in Glorietta Bay at approximately 32°40.68' N, 117°10.18' W. The safety zone will encompass all navigable waters within 1200 feet of the