

result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

C. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the direct final 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

This direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 2. Revise § 601.8 to read as follows:

§ 601.8 Publication of revocation.

The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.

Dated: March 25, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10244 Filed 5–4–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0024]

Drawbridge Operation Regulation; High Street Drawbridge, Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the High Street drawbridge across the Oakland Inner Harbor, mile 6.0, at Alameda, CA. The deviation is necessary to allow seismic retrofitting of the bridge. This deviation allows single leaf operation of the double leaf, bascule style drawbridge, during the deviation period.

DATES: This deviation is effective from 12:01 a.m. on May 1, 2009 until 11:59 p.m. on August 31, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of the docket USCG–2009–0024 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–2009–0024 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 rule call David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516. If you have questions on viewing the docket, call Renee Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The County of Alameda requested a temporary change to the operation of the High Street drawbridge across the Oakland Inner Harbor, mile 6.0, at Alameda, CA. The High Street drawbridge navigation span provides a horizontal clearance of 244 feet between pier fenders. During single leaf operation, horizontal clearance is reduced to approximately 100 feet. The drawbridge provides a vertical clearance of 16 feet above Mean High Water in the closed-to-navigation position and unlimited vertical clearance in the open-to-navigation position. As required by 33 CFR 117.181, the draw shall open on signal; except that, from 8 a.m. to 9 a.m. and 4:30 p.m. to 6:30 p.m. Monday through Friday except Federal holidays, the draw need not be opened for the passage of vessels. However, the draw shall open during the above closed periods for vessels which must, for reasons of safety, move on a tide or slack water, if at least two hours notice is given. The waterway is navigated by commercial, recreational, emergency and law enforcement vessels.

Between the hours of 7 a.m. and 9 p.m. Monday through Thursday, and between the hours of 7 a.m. and 3:30 p.m. on Friday, the drawspan may be operated, one leaf at a time, while the opposite leaf is seismically retrofitted. The drawbridge will be operated in the normal double leaf operation mode at night and on weekends, when work is not actually being performed on the bridge. The starting and ending dates for the project are from 12:01 a.m. on May

1, 2009 until 11:59 p.m. on August 31, 2009. This temporary deviation has been coordinated with the waterway users. The largest tug and barge combination on the waterway will be able to continue navigating safely through the bridge. Recreational and other waterway traffic will not be negatively impacted by the project.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 16, 2009.

P.F. Zukunft,

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

[FR Doc. E9-10241 Filed 5-4-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0016]

RIN 1625-AA00

Safety Zone; Allegheny River Mile Marker 0.4 to Mile Marker 0.6, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the waters of the Allegheny River from mile marker 0.4 to mile marker 0.6, extending the entire width of the river. This safety zone is needed to protect spectators and vessels from the hazards associated with the Pittsburgh Pirates Fireworks Display. Entry into this zone is prohibited, unless specifically authorized by the Captain of the Port Pittsburgh or a designated representative.

DATES: This rule is effective from 8:30 p.m. on May 2, 2009 until 11:30 p.m. on September 26, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0016 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-2009-0016 in the Docket ID box,

pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying two locations: 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, and the U.S. Coast Guard Marine Safety Unit Pittsburgh, Suite 1150 Town Place, 100 Forbes Avenue, Pittsburgh, PA 15222, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Lieutenant Junior Grade Douglas Kang Marine Safety Unit Pittsburgh, telephone 412-644-5808. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

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**. Publishing an NPRM and delaying its effective date would be contrary to public interest because immediate action is needed to protect participant and spectator craft from the hazards associated with the Pittsburgh Pirates Fireworks Display.

Background and Purpose

The Captain of the Port Pittsburgh is establishing a safety zone for the waters of the Allegheny River from mile marker 0.4 to mile marker 0.6, extending the entire width of the river at the conclusion of each Pittsburgh Pirates baseball game involving a fireworks display. A safety zone is needed to protect participant and spectator craft from the hazards associated with the Pittsburgh Pirates Fireworks Display.

Discussion of Rule

The Captain of the Port Pittsburgh is establishing a safety zone for the waters of the Allegheny River from mile marker 0.4 to mile marker 0.6, extending the entire width of the river. Vessels shall not enter into, depart from, or move within this safety zone without permission from the Captain of the Port Pittsburgh or his authorized representative. Persons or vessels requiring entry into or passage through a safety zone must request permission from the Captain of the Port Pittsburgh, or a designated representative. They may be contacted on VHF-FM Channel

13 or 16, or through Coast Guard Sector Ohio Valley at 1-800-253-7465. This rule is effective from 8:30 p.m. on May 2, 2009 until 11:30 p.m. on September 26, 2009. However, this rule will only be enforced from 8:30 p.m. until 11:30 p.m. on days in which fireworks are scheduled to follow a Pittsburgh Pirates baseball game. These dates are: May 2, May 30, June 27, July 18, August 8, September 5, and September 26, 2009. The times of enforcement and scheduled game dates are based upon a prearranged schedule and may change. The Captain of the Port Pittsburgh will inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the planned schedule.

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 will be in effect for a short period of time and notifications to the marine community will be made through broadcast notices to mariners. The impacts on routine navigation are expected to be minimal.

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 vessels intending to transit that portion of the Allegheny River from mile marker 0.4 to mile marker 0.6, from 8:30 p.m. on May 2, 2009 until 11:30 p.m. on