authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.52 [Amended]

■ 2. Section 314.52 is amended in paragraph (a)(2) by removing ''at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)'' and by adding in its place ''7500 Standish Pl., Rockville, MD 20855''.

§ 314.53 [Amended]

■ 3. Section 314.53 is amended in paragraph (f) by removing ''at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)'' and by adding in its place ''7500 Standish Pl., Rockville, MD 20855''.

§ 314.95 [Amended]

■ 4. Section 314.95 is amended in paragraph (a)(2) by removing ''at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)'' and by adding in its place ''7500 Standish Pl., Rockville, MD 20855''.

Dated: July 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17680 Filed 7–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2009–0659]

RIN 1625–AA08

Special Local Regulations for Marine Events; Port Huron to Mackinac Island Sail Race

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will enforce a special local regulation for the annual Port Huron to Mackinac Island Sail Race. This action is necessary to safely control vessel movements in the vicinity of the race starting point and provide for the safety of the general boating public and commercial shipping. During this period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander (''PATCOM'').

DATES: This rule is effective from 9 a.m. through 4 p.m. on July 25, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0659 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–2009–0659 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 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 concerning this temporary rule, call or e-mail Mr. Frank Jennings, Jr., Enforcement Branch, Ninth Coast Guard District, 1240 East 9th Street, Cleveland, OH, via e-mail at: *frank.t.jennings@uscg.mil* or by phone at: (216) 902–6094. 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 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 special local regulation pertaining to this annual race was previously published in the Code of Federal Regulations, but inadvertently removed during the most recent revision to 33 CFR 100.901. Because this is an annual race, held in the same location, local maritime interests are already familiar with the provisions of these regulations. Based on the late discovery of the missing permanent rule, the hazards associated with marine regattas within Port Huron and the short amount of time until the event, delaying publication of this regulation would be contrary to the public interest.

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 special local regulation pertaining to this annual race was previously published in the Code of Federal Regulations, but inadvertently removed during the most recent revision to 33 CFR 100.901. Because this is an annual race, held in the same location, local maritime interests are already familiar with the provisions of these regulations. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this operation and immediate action is necessary to prevent possible loss of life or property.

Background and Purpose

Special local regulations are necessary to safely control vessel movements in the vicinity of the race starting point and provide for the safety of the general boating public and commercial shipping. The Captain of the Port Detroit has determined that the start of the Port Huron to Mackinac Island Sail Race does pose significant risks to public safety and property. The likely combination of congested waterways, vessels engaged in a regatta, and fast currents could easily result in serious injuries or fatalities.

Discussion of Rule

The Coast Guard will enforce special local regulations for the annual Port Huron to Mackinac Sail Race from 9 a.m. until 4 p.m. on July 25, 2009. The special local regulations apply to the waters of the Black River, St. Clair River and lower Lake Huron from:

Latitude	Longitude
42°58.8′ N	082°26′ W, to
42°58.4′ N	082°24.8′ W, thence northward along the International Boundary to
43°02.8′ N	082°23.8′ W, to
43°02.8′ N	082°26.8′ W, thence southward along the U.S. shoreline to
42°58.9′ N	082°26′ W, thence to
42°58.8′ N	082°26′ W.

[DATUM: NAD 1983].

In order to ensure the safety of spectators and participating vessels, the special local regulations will be in effect for the day of the start of the event. The Coast Guard will patrol the race area under the direction of a designated Coast Guard Patrol Commander

(''PATCOM''). Vessels desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer. The PATCOM may be contacted on Channel 16 (156.8 MHZ) by the call sign ''Coast Guard Patrol Commander.'' Vessels will be operated at a no wake speed to reduce the wake to a minimum, and in a manner which will not endanger participants in the event or any other craft. The rules contained in the above two sentences shall not apply to participants in the event or vessels of the patrol operating in the performance of their assigned duties.

In the event these special local regulations affect shipping, commercial vessels may request permission from the PATCOM to transit the area of the event by hailing call sign ''Coast Guard Patrol Commander'' on Channel 16 (156.8 MHZ).

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.

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 or anchor in a portion of the Black River, St. Clair River and lower Lake Huron from 9 a.m. until 4 p.m. July 25, 2009.

These special local regulations will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be enforced for only 7 hours on a weekend when the majority of vessel traffic transiting the area is recreational. Vessel traffic will be allowed to pass through the area of the race start with the permission of the Coast Guard patrol commander. Before the effective period, the Coast Guard will issue maritime advisories widely 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 offered to assist small entities in understanding the rule so that they could 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 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 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 create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate Tribal concerns. We have determined that these regulations and fishing rights protection need not be incompatible. We have also determined that 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. Nevertheless, Indian Tribes that have questions concerning the provisions of this Rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

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 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded 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 (34)(h), of the Instruction. This rule involves the enforcement of special local regulations, pursuant to 33 CFR 100, for the annual Port Huron to Mackinac Island Sail Race, July 25, 2009 at 9 a.m. to July 25, 2009 at 4 p.m. This action is necessary to safely control vessel movements in the vicinity of the start of the race and provide for the safety of the general boating public and commercial shipping. Regulations will be in effect for seven hours on the day the event starts. The Coast Guard will patrol the race area under the direction of a designated Coast Guard Patrol Commander.

An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. A new temporary § 100.35T09–0659 is added as follows:

§ 100.35T09–0659 Special Local Regulations for Marine Events; Port Huron to Mackinac Island Sail Race.

(a) *Location.* The special local regulations apply to the waters of the Black River, St. Clair River and lower Lake Huron from:

Latitude	Longitude
42°58.8′ N	082°26′ W, to
42°58.4′ N	082°24.8′ W, thence northward along the International Boundary to
43°02.8′ N	082°23.8′ W, to
43°02.8′ N	082°26.8′ W, thence southward along the U.S. shoreline to
42°58.9′ N	082°26′ W, thence to
42°58.8′ N	082°26′ W.

[DATUM: NAD 1983].

(b) *Effective period.* This rule is effective from 9 a.m. to 4 p.m. on July 25, 2009.

(c) *Regulations.*

(1) In accordance with the general regulations in section 100.35 of this part, the Coast Guard will patrol the regatta area under the direction of a designated Coast Guard Patrol Commander (''PATCOM''). The PATCOM may be contacted on Channel 16 (156.8 MHz) by the call sign ''Coast Guard Patrol Commander.'' Vessels desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer.

(2) Vessels will be operated at a no wake speed to reduce the wake to a minimum, and in a manner which will not endanger participants in the even or any other craft. The rules in this subparagraph shall not apply to participants in the event or vessels of the patrol operating in the performance of their assigned duties.

(3) The PATCOM may direct the anchoring, mooring or movement of any boat or vessel within the regatta area. A succession of sharp, short signals by whistle or horn from vessels patrolling the area under the direction of the U.S. Coast Guard PATCOM shall serve as a signal to stop. Vessels so signaled shall stop and shall comply with the orders of the PATCOM. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(4) The PATCOM may establish vessel size and speed limitations and operating conditions. The PATCOM may restrict vessel operation within the regatta area to vessels having particular operating characteristics. The PATCOM may terminate the marine event or the operation of vessel at any time it is deemed necessary for the protection of life and property.

Dated: July 10, 2009.

F.M. Midgette,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. E9–17748 Filed 7–23–09; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0578]

Drawbridge Operation Regulations; East River, New York City, NY, Maintenance

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Roosevelt Island Bridge across the East River, mile 6.4, at New York City, New York. Under this temporary deviation the bridge may remain in the closed position for one month to facilitate completion of ongoing bridge maintenance. Vessels that can pass under the draw without a bridge opening may do so at all times.

DATES: This deviation is effective from July 24, 2009 through August 15, 2009.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–0578 and are available online at *http://www.regulations.gov,* selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0578 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