

File No.	Sponsor	Product name	21 CFR section
104-606	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.	Dexamethasone Sodium Phosphate Injection	522.540
139-633	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550.	WILDNIL (carfentanil citrate) Injection	522.300

Therefore, under authority delegated to the Commissioner of Food and Drugs, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 047-055, 104-606, and 139-633, and all supplements and amendments thereto, is hereby withdrawn, effective April 9, 2018.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06357 Filed 3-29-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2018-0235]

RIN 1625-AA08

Special Local Regulation; Wyandotte Rowing Regatta; Detroit River, Trenton Channel; Wyandotte, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for certain waters of the Detroit River, Trenton Channel, Wyandotte, MI. This action is necessary and is intended to ensure safety of life on navigable waters to be used for a rowing event immediately prior to, during, and immediately after this event.

DATES: This temporary final rule is effective from 8 a.m. until 11 a.m. on April 21, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0235 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary

rule, call or email Tracy Girard, Prevention Department, Sector Detroit, Coast Guard; telephone 313-568-9564, or email Tracy.M.Girard@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
COTP Captain of the Port
U.S.C. United States Code

II. Background Information and Regulatory History

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 doing so would be impracticable. The Coast Guard did not receive the final details of this rowing event until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard's ability to protect participants, mariners and vessels from the hazards associated with this event. We are issuing this rule under 5 U.S.C. 553(d)(3), as the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register** for the same reason noted above.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Detroit (COTP) has determined that the likely combination of recreation vessels, commercial vessels, and an unknown number of spectators in close proximity to a youth rowing regatta along the water pose extra and unusual hazards to public

safety and property. Therefore, the COTP is establishing a Special Local Regulation around the event location to help minimize risks to safety of life and property during this event.

IV. Discussion of the Rule

This rule establishes a temporary special local regulation from 8 a.m. until 11 a.m. on April 21, 2018. In light of the aforementioned hazards, the COTP has determined that a special local regulation is necessary to protect spectators, vessels, and participants. The special local regulation will encompass the following waterway: All waters of the Detroit River, Trenton Channel between the following two lines going from bank-to-bank: The first line is drawn directly across the channel from position 42°11.0' N, 083°09.4' W (NAD 83); the second line, to the north, is drawn directly across the channel from position 42°11.7' N, 083°08.9' W (NAD 83).

An on-scene representative of the COTP may permit vessels to transit the area when no race activity is occurring. The on-scene representative may be present on any Coast Guard, state, or local law enforcement vessel assigned to patrol the event. Vessel operators desiring to transit through the regulated area must contact the Coast Guard Patrol Commander to obtain permission to do so. The COTP or his designated on-scene representative may be contacted via VHF Channel 16 or at 313-568-9560.

The COTP or his designated on-scene representative will notify the public of the enforcement of this rule by all appropriate means, including a Broadcast Notice to Mariners and Local Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the special local regulation. Vessel traffic will be able to safely transit around this special local regulation zone which will impact a small designated area of the Detroit River from 8 a.m. to 11 a.m. April 21, 2018. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF-FM marine channel 16 about the special local regulation and the rule allows vessels to seek permission to enter the area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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.

While some owners or operators of vessels intending to transit the special local regulation may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 rule. 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 the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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 (adjusted for inflation) 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.

F. Environment

We have analyzed this rule under Department of Homeland Security

Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting four hours that will prohibit entry into a designated area. It is categorically excluded from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and record keeping 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. Add § 100.T09–0235 to read as follows:

§ 100.T09–0235 Special Local Regulation; Wyandotte Rowing Regatta; Detroit River, Trenton Channel, Wyandotte, MI.

(a) *Location.* A regulated area is established to encompass the following waterway: All waters of the Detroit River, Trenton Channel between the following two lines going from bank-to-bank: The first line is drawn directly across the channel from position 42°11.0′ N, 083°09.4′ W (NAD 83); the second line, to the north, is drawn directly across the channel from position 42°11.7′ N, 083°08.9′ W (NAD 83).

(b) *Enforcement period.* The regulated area described in paragraph (a) will be enforced from 8 a.m. until 11 a.m. on April 21, 2018.

(c) *Special local regulations.* (1) Vessels transiting through the regulated area are to maintain the minimum speeds for safe navigation.

(2) Vessel operators desiring to operate in the regulated area must contact the Coast Guard Patrol Commander to obtain permission to do so. The Captain of the Port Detroit (COTP) or his on-scene representative may be contacted via VHF Channel 16 or at 313-568-9560. Vessel operators given permission to operate within the regulated area must comply with all directions given to them by the COTP or his on-scene representative.

(3) The "on-scene representative" of the COTP Detroit is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port Detroit to act on his behalf.

(4) Vessel operators shall contact the COTP Detroit or his on-scene representative to obtain permission to enter or operate within the special local regulation. The COTP Detroit or his on-scene representative may be contacted via VHF Channel 16 or at 313-568-9464. Vessel operators given permission to enter or operate in the regulated area must comply with all directions given to them by the COTP Detroit or his on-scene representative.

Dated: March 23, 2018.

Jeffrey W. Novak,

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

[FR Doc. 2018-06466 Filed 3-29-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0227]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Tower Drawbridge across the Sacramento River, mile 59.0 at Sacramento, CA. The deviation is necessary to allow the local community to participate in the Sacramento Giant Race 5K/10K run/walk. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 7 a.m. to 12:30 p.m. on April 21, 2018.

ADDRESSES: The docket for this deviation, USCG-2018-0227, is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Carl T. Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510-437-3516, email Carl.T.Hausner@uscg.mil.

SUPPLEMENTARY INFORMATION: The California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over the Sacramento River, at Sacramento, CA. The drawbridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw operates as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position 7 a.m. to 12:30 p.m. on April 21, 2018, to allow the community to participate in the Sacramento Giant Race 5K/10K run/walk. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: March 27, 2018.

Carl T. Hausner,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2018-06461 Filed 3-29-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0241]

Drawbridge Operation Regulation; Reynolds Channel, Long Beach, New York

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the MTA Long Island Railroad Bridge across the Reynolds Channel, mile 4.4, at Long Beach, New York. This temporary deviation is necessary to replace bridge timbers. This deviation allows the bridge to remain in the closed position.

DATES: This deviation is effective from 12:01 a.m. on April 7, 2018 to 12:01 a.m. on April 30, 2018.

ADDRESSES: The docket for this deviation, USCG-2018-0241 is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Stephanie E. Lopez, Project Officer, First Coast Guard District, telephone (212) 514-4335, email Stephanie.E.Lopez@uscg.mil.

SUPPLEMENTARY INFORMATION: The owner of the bridge, the MTA Long Island Railroad, requested a temporary deviation to facilitate the replacement of bridge timbers. The Long Island Railroad Bridge across the Reynolds Channel, mile 4.4, has a vertical clearance in the closed position of 14 feet at mean high water. The existing bridge operating regulations are found at 33 CFR 117.5.

This temporary deviation allows the Long Island Railroad Bridge to remain in the closed position as follows:

12:01 a.m. on April 7 to 4 a.m. on April 9;

12:01 a.m. on April 14 to 4 a.m. on April 16;

12:01 a.m. on April 21 to 12:01 a.m. on April 23; and

12:01 a.m. on April 28 to 12:01 a.m. on April 30.

The waterway is transited by commercial and recreational traffic. Coordination with the waterway users has indicated no objection to the proposed closure of the drawbridge.