

between 9 a.m. and 4 p.m., Monday through Friday.

### IX. Section 301(l) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(l) of the FD&C Act (21 U.S.C. 331(l)). Section 301(l) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in section 301(l)(1) to (l)(4) of the FD&C Act applies. In its review of this petition, FDA did not consider whether section 301(l) of the FD&C Act or any of its exemptions apply to the laser-etching source. Accordingly, this final rule should not be construed to be a statement that a food that has been laser etched, if introduced or delivered for introduction into interstate commerce, would not violate section 301(l) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

### X. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, May 16, 2007.
2. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, November 19, 2008.
3. Memorandum from Khan, Toxicology Team, Division of Petition Review, to Johnston, Regulatory Group II, Division of Petition Review, April 20, 2010.
4. Memorandum from Losikoff, Division of Seafood Safety, and Mahovic, Produce Safety Staff, to Johnston, Regulatory Group II, Division of Petition Review, August 15, 2011.

### List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

### PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 2. Section 179.43 is added to subpart B to read as follows:

#### § 179.43 Carbon dioxide laser for etching food.

Carbon dioxide laser light may be safely used for etching information on the surface of food under the following conditions:

(a) The radiation source consists of a carbon dioxide laser designed to emit pulsed infrared radiation with a wavelength of 10.6 micrometers such that the maximum energy output of the laser does not exceed  $9.8 \times 10^{-3}$  joules per square centimeter ( $J/cm^2$ );

(b) The carbon dioxide laser shall be used only for etching information on the skin of fresh, intact citrus fruit, providing the fruit has been adequately washed and waxed prior to laser etching, and the etched area is immediately rewaxed after treatment; and

(c) The maximum total energy to which the etched citrus fruit is exposed from the use of the carbon dioxide laser shall not exceed  $1.5 \times 10^{-3}$  J, and the maximum total etched surface area of the citrus fruit shall not exceed 0.122  $cm^2$ .

Dated: June 5, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2012-0197]

RIN 1625-AA08

#### Special Local Regulations for Marine Events, Swim Event; Lake Gaston, Littleton, NC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard will establish a Special Local Regulation for "The Crossing" swim event to be held on the waters of Lake Gaston, adjacent to the Eaton Ferry Bridge in Littleton, North Carolina. This Special Local Regulation is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic on Lake Gaston under the Eaton Ferry Bridge and within 100 yards west of the bridge during the swim event.

**DATES:** This rule is effective from 7:30 a.m. to Noon on August 11, 2012.

**ADDRESSES:** Documents mentioned in this preamble are part of docket [USCG-2012-0197]. To view documents mentioned in this preamble as being available in the docket, go to <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 rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 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 or email BOSN3 Joseph M. Edge, U.S. Coast Guard Sector North Carolina; telephone 252-247-4525, email [Joseph.M.Edge@uscg.mil](mailto:Joseph.M.Edge@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

#### SUPPLEMENTARY INFORMATION:

#### Table of Acronyms

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

#### A. Regulatory History and Information

The regulatory history for this action includes both a Notice of proposed

rulemaking and Temporary final rule published in the **Federal Register** on May 24, 2011 and July 7, 2011 respectively. On April 3, 2012, we published a notice of proposed rulemaking (NPRM) entitled "Special local regulations for marine events, Swim Event, Lake Gaston; Littleton, NC" in the **Federal Register** (77 FR 19954). We received no comments on the proposed rule. No public meeting was requested, and none was held.

### B. Basis and Purpose

On August 11, 2012 from 7:30 a.m. to Noon, the Organization to Support the Arts, Infrastructure, and Learning on Lake Gaston, also known as O'SAIL, will sponsor "The Crossing" on the waters of Lake Gaston, adjacent to Littleton, North Carolina. The swim event will consist of approximately 350 swimmers entering Lake Gaston at the Morning Star Marina on the south bank of Lake Gaston, west of the Eaton Ferry Bridge, and swimming north along the western side of Eaton Ferry Bridge to the Waterview Restaurant. A fleet of spectator vessels is expected to gather near the event site to view the competition. To provide for the safety of participants, spectators and other transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during this event.

In an effort to enhance safety of event participants the channel in the vicinity of Eaton Ferry Bridge will remain closed during the event on August 11, 2012 from 7:30 a.m. to Noon. The Coast Guard will temporarily restrict access to this section of Lake Gaston during the event.

### C. Discussion of Comments, Changes and the Final Rule

The Coast Guard did not receive comments in response to the notice of proposed rulemaking (NPRM) published in the **Federal Register**. Accordingly, the Coast Guard is establishing special local regulations on the specified navigable waters listed in this regulation.

### D. 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.

#### 1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving

Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

Although this regulation will restrict access to the area, the effect of this rule will not be significant because the regulated area will be in effect for a limited time, from 7:30 a.m. to 12 p.m. (Noon), on August 11, 2012. The Coast Guard will provide advance notification via maritime advisories so mariners can adjust their plans accordingly. The regulated area will apply only to the section of Lake Gaston in the immediate vicinity of Eaton Ferry Bridge. Coast Guard vessels enforcing this regulated area can be contacted on marine band radio VHF-FM channel 16 (156.8 MHz).

#### 2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601-612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard received no comments from the Small Business Administration on this rule. 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 specified portion of Lake Gaston from 7:30 a.m. to Noon on August 11, 2012.

This rule will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will only be in effect for four and one-half hours from 7:30 a.m. to Noon. The regulated area applies only to the section of Lake Gaston in the vicinity of Eaton Ferry Bridge. Vessel traffic may be allowed to pass through the regulated area with the permission of the Coast Guard Patrol Commander. In the case where the Patrol Commander authorizes passage through the regulated area, vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the swim course. The Patrol Commander will allow non-participating vessels to transit the event area once all swimmers are safely clear of navigation channels and vessel traffic areas. Before the enforcement period, we will issue maritime advisories so mariners can adjust their plans accordingly.

#### 3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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**, above.

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 Enforcement 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.

#### 4. 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).

#### 5. Federalism

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 determined that this rule does not have implications for federalism.

#### 6. 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.

#### 7. 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.

#### 8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### 9. 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.

#### 10. 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.

#### 11. 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.

#### 12. Energy Effects

This action is not a "significant energy action" under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

#### 13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### 14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (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 implementation of regulations within 33 CFR part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative impact on the safety or other interest of waterway users and shore side activities in the event area. This special local regulation is necessary to provide for the safety of the general public and event participants from potential hazards associated with movement of vessels near the event area. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2-1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

#### 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. Add a temporary § 100.35–T05–0197 to read as follows:

#### § 100.35–T05–0197 Lake Gaston, Enterprise, NC.

(a) *Regulated area.* The following location is a regulated area: All waters of Lake Gaston directly under the Eaton Ferry Bridge, latitude 36°31'06" North, longitude 077°57'37" West, and within 100 yards of the western side of the bridge at Littleton, North Carolina. All coordinates reference Datum NAD 1983.

(b) *Definitions.* (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the U. S. Coast Guard who has been designated by the Commander, Coast Guard Sector North Carolina.

(2) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector North Carolina with

a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Participant* means all vessels participating in the "The Crossing" swim event under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector North Carolina.

(4) *Spectator* means all persons and vessels not registered with the event sponsor as participants or official patrol.

(c) *Special local regulations.* (1) The Coast Guard Patrol Commander will control the movement of all vessels in the vicinity of the regulated area. When hailed or signaled by an official patrol vessel, a vessel approaching the regulated area shall immediately comply with the directions given. Failure to do so may result in termination of voyage and citation for failure to comply.

(2) The Coast Guard Patrol Commander may terminate the event, or the operation of any support vessel participating in the event, at any time it is deemed necessary for the protection of life or property. The Coast Guard may be assisted in the patrol and enforcement of the regulated area by other Federal, State, and local agencies.

(3) Vessel traffic, not involved with the event, may be allowed to transit the regulated area with the permission of the Patrol Commander. Vessels that desire passage through the regulated area shall contact the Coast Guard Patrol Commander on VHF–FM marine band radio for direction. Only participants and official patrol vessels are allowed to enter the regulated area.

(4) All Coast Guard vessels enforcing the regulated area can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22 (157.1 MHz). The Coast Guard will issue marine information broadcast on VHF–FM marine band radio announcing specific event date and times.

(d) *Enforcement period.* This section will be enforced from 7:30 a.m. to (Noon) 12 p.m. on August 11, 2012.

Dated: May 30, 2012.

#### A. Popiel,

*Captain, U.S. Coast Guard, Captain of the Port North Carolina.*

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