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Steven L. Vale,

*Acting Manager, Operations Support Group,
Western Service Center.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2011-C-0050]

D&C Red No. 6 and D&C Red No. 7; Change in Specification; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 7, 2012, for the final rule that published in the **Federal Register** of July 6, 2012 (77 FR 39921) and that revised the requirements for D&C Red No. 6 and D&C Red No. 7 by replacing the current specification for “Ether-soluble matter” with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol.

DATES: *Effective Date Confirmed:* August 7, 2012.

FOR FURTHER INFORMATION CONTACT:

Teresa A. Croce, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1281.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 6, 2012, FDA amended the color additive regulations in §§ 74.1306 and 74.1307 (21 CFR 74.1306 and 74.1307) by replacing the current specification for “Ether-soluble matter” with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol. FDA also removed Appendix A in 21 CFR part 74, which pertains to the ether-soluble matter specification. The changes to §§ 74.1306 and 74.1307 also affect the color additive regulations in §§ 74.2306 and 74.2307 (21 CFR 74.2306 and 74.2307) because the identity and specifications in §§ 74.1306 and 74.1307 are referenced by §§ 74.2306 and 74.2307.

FDA gave interested persons until August 6, 2012, to file objections or requests for a hearing. The Agency

received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of July 6, 2012, should be confirmed.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, notice is given that no objections or requests for a hearing were filed in response to the July 6, 2012, final rule. Accordingly, the amendments issued thereby became effective August 7, 2012.

Dated: September 5, 2012.

Dennis M. Keefe,

*Director, Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.*

[FR Doc. 2012-22296 Filed 9-10-12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2012-0722]

RIN 1625-AA08

Safety Zone; Miami Paddle Challenge, Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Biscayne Bay located west of Key Biscayne and south of Rickenbacker Causeway in Miami, Florida during the Miami Paddle Challenge, a series of paddle boat races. The Miami Paddle Challenge is scheduled to take place on Sunday, September 29, 2012. The temporary safety zone is necessary for the safety of race participants, participant vessels, spectators, and the general public during the event. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule is effective and will be enforced from 6 a.m. through 4 p.m. on September 29, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2012-7222 and are available online by going to <http://www.regulations.gov>, inserting

USCG-2012-7222 in the “SEARCH” box, and then clicking “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 temporary final rule, call or email Lieutenant Junior Grade Mike H. Wu, Sector Miami Prevention Department, Coast Guard; telephone (305) 535-7576, email mike.h.wu@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 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 a safety zone was not determined to be necessary until August 1, 2012. As a result, the Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the Miami Paddle Challenge. Any delay in the effective date of this rule would be contrary to the public interest as immediate action is needed to minimize potential danger to the public, race participants, and spectator craft.

For the same reason discussed above, 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**.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard’s authority to establish regulated navigation areas and other

limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to provide for the safety of life on navigable waters of the United States during the Miami Paddle Challenge.

C. Discussion of the Final Rule

On Sunday, September 29, 2012, Miami Children's Hospital is sponsoring the Miami Paddle Challenge. Over 150 paddle boats are expected to participate in the event. Participant paddle boats will include: kayaks, surfskis, paddleboards, outriggers, sculls, canoes, dories, and dragon boats.

The temporary safety zone encompasses certain waters of Biscayne Bay located west of Key Biscayne and south of Rickenbacker Causeway in Miami, Florida. The safety zone will be enforced from 6 a.m. until 4 p.m. on September 29, 2012.

Non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Miami or a designated representative. Non-participant persons and vessels desiring to enter, transit through, anchor in, or remain within the safety zone may contact the Captain of the Port Miami by telephone at 305–535–4472, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

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 that Order.

The economic impact of this rule is not significant for the following reasons: (1) The safety zone will be enforced for only ten hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the event area without authorization from the Captain of the Port Miami or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the event area during the enforcement period if authorized by the Captain of the Port Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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 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 may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of the Biscayne Bay encompassed within the safety zone from 6 a.m. until 4 p.m. on September 29, 2012. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

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 the rule so that they can better evaluate its effects on them and participate in the rulemaking process. 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 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 calls for no 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 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 would not create an environmental risk to health or risk to safety that might 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.ID, 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)(g), of the Instruction. This rule involves the establishment of a temporary safety zone to protect the public on navigable waters of the United States. An environmental analysis checklist 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 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.20T07–0722 to read as follows:

§ 165.20T07–0722 Safety zone; Miami Paddle Challenge, Biscayne Bay, Miami, FL.

(a) *Biscayne Bay, Florida.* All waters of Biscayne Bay located west of Key Biscayne and south of Rickenbacker Causeway encompassed within an imaginary line connecting the following points: starting at Point 1 in position 25°44′43″ N, 80°11′40″ W; thence southwest to Point 2 in position 25°40′29″ N, 80°14′58″ W; thence northwest to Point 3 in position 25°40′39″ N, 80°15′14″ W; thence northeast to Point 4 in position 25°44′45″ N, 80°11′59″ W; thence east back to origin. All coordinates are North American Datum 1983.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) Regulations.

(1) Non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Miami or a designated representative. Non-participant persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Miami by telephone at 305–535–4472, or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port

Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(2) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective Date.* This rule is effective from 6 a.m. until 4 p.m. on September 29, 2012.

Dated: August 23, 2012.

C.P. Scraba,

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

[FR Doc. 2012–22294 Filed 9–10–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2012–0280; FRL–9724–8]

Approval and Promulgation of Implementation Plans; Virginia; Revisions to the State Implementation Plan Approved by EPA Through Letter Notice Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: EPA is taking final action on administrative changes to the Virginia State Implementation Plan (SIP). The changes consist of revised regulatory citations found in Virginia’s regulations pertaining to municipal solid waste landfills and open burning which EPA previously approved through a Letter Notice. EPA has determined that this action falls under the “good cause” exemption in the Administrative Procedure Act (APA). This exemption in the APA authorizes agencies to dispense with public participation and to make an action effective immediately, thereby avoiding the 30-day delayed effective date otherwise provided for in the APA.

DATES: This action is effective September 11, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2012–0280. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as