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Steven L. Vale,

*Acting Manager, Operations Support Group,
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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