

the period of exclusive marketing of another drug, FDA will so notify the sponsor in writing.

■ 15. Section 316.34 is revised to read as follows:

§ 316.34 FDA recognition of exclusive approval.

(a) FDA will send the sponsor (or, the permanent-resident agent, if applicable) timely written notice recognizing exclusive approval once the marketing application for a designated orphan-drug product has been approved, if the same drug has not already been approved for the same use or indication. The written notice will inform the sponsor of the requirements for maintaining orphan-drug exclusive approval for the full 7-year term of exclusive approval.

(b) When a marketing application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for a designated orphan drug that qualifies for exclusive approval, FDA will publish in its publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations" information identifying the sponsor, the drug, and the date of termination of the orphan-drug exclusive approval. A subscription to this publication and its monthly cumulative supplements is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, and is also available online at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

(c) If a drug is otherwise the same drug as a previously approved drug for the same use or indication, FDA will not recognize orphan-drug exclusive approval if the sponsor fails to demonstrate upon approval that the drug is clinically superior to the previously approved drug.

■ 16. Section 316.50 is revised to read as follows:

§ 316.50 Guidance documents.

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the **Federal Register**. A request for a copy of the list should be directed to the Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Dated: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2013-0369]

RIN 1625-AA08

Special Local Regulation; Kelley's Island Swim, Lake Erie; Kelley's Island, Lakeside, OH

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will regulate vessel movement in portions of Lake Erie during the annual Kelley's Island Swim from. This special local regulated area is necessary to protect swimmers from vessel traffic.

DATES: The regulations in 33 CFR 100.921 will be enforced between 7 a.m. and 11 a.m. on July 10, 2013.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email MST2 Annaliese Ennis, Assistant Waterways Branch Chief, Marine Safety Unit Toledo, 420 Madison Ave., Suite 700, Toledo, OH 43604; telephone (419) 418-6041; email Annaliese.K.Ennis@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations listed in 33 CFR 100.921 Special Local Regulation; Kelley's Island Swim, Lake Erie, Lakeside, OH, which was published in the December 3, 2012, issue of the **Federal Register** (77 FR 71531). These special local regulations will be enforced from 7 a.m. until 11 a.m. on July 10, 2013. Pursuant to 33 U.S.C. 1236 and 33 CFR 27.3, those who fail to comply with the special local regulations in 33 CFR 100.921 during this enforcement period will be subject to a civil penalty of up to \$8,000.

Under the provisions of 33 CFR 100.921, vessels transiting within the regulated area shall travel at a no-wake speed and remain vigilant for event participants and safety craft. Additionally, vessels shall yield right-of-way for event participants and event safety craft and shall follow directions given by the Coast Guard's on-scene representative or by event

representatives during the event. The "on-scene representative" of the Captain of the Port Detroit is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port Detroit to act on his behalf. The on-scene representative of the Captain of the Port Detroit will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port, Sector Detroit or his designated on scene representative may be contacted via VHF Channel 16.

This notice is issued under the authority of 33 CFR 100.921 and 5 U.S.C. 552(a).

Dated: May 28, 2013.

J. E. Ogden,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG-2012-1057]

Special Local Regulations and Safety Zones; Recurring Events in Northern New England

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce the events outlined in Tables 1 and 2 taking place throughout the Sector Northern New England Captain of the Port Zone. This action is necessary to protect marine traffic and spectators from the hazards associated with powerboat races, regattas, boat parades, rowing and paddling boat races, swim events, and fireworks displays. During the enforcement period, no person or vessel may enter the Special Local Regulation area or Safety Zone without permission of the Captain of the Port.

DATES: The marine events listed in 33 CFR 100.120 and 33 CFR 165.171 will take place during the times and dates specified in Tables 1 and 2 in

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Ensign Elizabeth V. Morris, Waterways Management Division at Coast Guard Sector Northern New England, telephone 207-767-0398, email Elizabeth.V.Morris@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local