

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.*

[FR Doc. 2013-13930 Filed 6-11-13; 8:45 am]

**BILLING CODE 4160-01-P**

**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](mailto: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.*

[FR Doc. 2013-13906 Filed 6-11-13; 8:45 am]

**BILLING CODE 9110-04-P**

**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](mailto:Elizabeth.V.Morris@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the Special Local

Regulations and Safety Zones listed in 33 CFR 100.120 and 33 CFR 165.171. These regulations will be enforced for

the duration of each event, on or about the dates indicated in TABLES 1 and 2.

TABLE 1—(33 CFR 100.120)

JUNE	
Charlie Begin Memorial Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Boothbay Harbor Lobster Boat Race Committee.</li> <li>• Date: June 15, 2013.</li> <li>• Time: 9 a.m. to 3 p.m.</li> <li>• Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of John’s Island within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>43°50’04” N, 069°38’37” W.</li> <li>43°50’54” N, 069°38’06” W.</li> <li>43°50’49” N, 069°37’50” W.</li> <li>43°50’00” N, 069°38’20” W.</li> </ul> </li> </ul>
Rockland Harbor Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Rockland Harbor Lobster Boat Race Committee.</li> <li>• Date: June 16, 2013.</li> <li>• Time: 9 a.m. to 4 p.m.</li> <li>• Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of the Rockland Breakwater Light within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>44°05’59” N, 069°04’53” W.</li> <li>44°06’43” N, 069°05’25” W.</li> <li>44°06’50” N, 069°05’05” W.</li> <li>44°06’05” N, 069°04’34” W.</li> </ul> </li> </ul>
Windjammer Days Parade of Ships .....	<ul style="list-style-type: none"> <li>• Event Type: Tall Ship Parade.</li> <li>• Sponsor: Boothbay Region Chamber of Commerce.</li> <li>• Date: June 26, 2013.</li> <li>• Time: 1 p.m. to 5 p.m.</li> <li>• Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of Tumbler’s Island within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>43°51’02” N, 069°37’33” W.</li> <li>43°50’47” N, 069°37’31” W.</li> <li>43°50’23” N, 069°37’57” W.</li> <li>43°50’01” N, 069°37’45” W.</li> <li>43°50’01” N, 069°38’31” W.</li> <li>43°50’25” N, 069°38’25” W.</li> <li>43°50’49” N, 069°37’45” W.</li> </ul> </li> </ul>
JULY	
Searsport Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Searsport Lobster Boat Race Committee.</li> <li>• Date: July 13, 2013.</li> <li>• Time: 9 a.m. to 3 p.m.</li> <li>• Location: The regulated area includes all waters of Searsport Harbor, Maine within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>44°26’50” N, 068°55’20” W.</li> <li>44°27’04” N, 068°55’26” W.</li> <li>44°27’12” N, 068°54’35” W.</li> <li>44°26’59” N, 068°54’29” W.</li> </ul> </li> </ul>
Mayor’s Cup Regatta .....	<ul style="list-style-type: none"> <li>• Event Type: Sailboat Parade.</li> <li>• Sponsor: Plattsburgh Sunrise Rotary.</li> <li>• Date: July 13, 2013.</li> <li>• Time: 8 a.m. to 5 p.m.</li> <li>• Location: The regulated area includes all waters of Cumberland Bay on Lake Champlain in the vicinity of Plattsburgh, New York within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>44°39’26” N, 073°26’25” W.</li> <li>44°41’27” N, 073°23’12” W.</li> </ul> </li> </ul>
Arthur Martin Memorial Regatta .....	<ul style="list-style-type: none"> <li>• Event Type: Rowing and Paddling Boat Race.</li> <li>• Sponsor: International Recreational Open Water Rowing Association.</li> <li>• Date: July 13, 2013.</li> <li>• Time: 9 a.m. to 1 p.m.</li> <li>• Location: The regulated area includes all waters of the Piscataqua River, in the vicinity of Kittery Point, Maine within the following points (NAD 83):                             <ul style="list-style-type: none"> <li>43°03’51” N, 070°41’55” W.</li> <li>43°04’35” N, 070°42’18” W.</li> <li>43°04’42” N, 070°43’15” W.</li> </ul> </li> </ul>

TABLE 1—(33 CFR 100.120)—Continued

Stonington Lobster Boat Races .....	<p>43°05'14" N, 070°43'12" W.  43°05'14" N, 070°43'06" W.  43°04'44" N, 070°43'11" W.  43°04'35" N, 070°42'13" W.  43°03'53" N, 070°41'40" W.</p> <ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Stonington Lobster Boat Race Committee.</li> <li>• Date: July 14, 2013.</li> <li>• Time: 9:30 a.m. to 4 p.m.</li> <li>• Location: The regulated area includes all waters of Stonington, Maine within the following points (NAD 83):  44°08'55" N, 068°40'12" W.  44°09'00" N, 068°40'15" W.  44°09'11" N, 068°39'42" W.  44°09'07" N, 068°39'39" W.</li> </ul>
The Challenge Race .....	<ul style="list-style-type: none"> <li>• Event Type: Rowing and Paddling Boat Race.</li> <li>• Sponsor: Lake Champlain Maritime Museum.</li> <li>• Date: July 14, 2013.</li> <li>• Time: 10 a.m. to 3 p.m.</li> <li>• Location: The regulated area includes all waters of Lake Champlain in the vicinity of Button Bay State Park within the following points (NAD 83):  44°12'25" N, 073°22'32" W.  44°12'00" N, 073°21'42" W.  44°12'19" N, 073°21'25" W.  44°13'16" N, 073°21'36" W.</li> </ul>
Yarmouth Clam Festival Paddle Race .....	<ul style="list-style-type: none"> <li>• Event Type: Rowing and Paddling Boat Race.</li> <li>• Sponsor: Maine Island Trail Association.</li> <li>• Date: July 20, 2013.</li> <li>• Time: 8:30 a.m. to 2 p.m.</li> <li>• Location: The regulated area includes all waters in the vicinity of the Royal River outlet and Lane's Island within the following points (NAD 83):  43°47'47" N, 070°08'40" W.  43°47'50" N, 070°07'13" W.  43°47'06" N, 070°07'32" W.  43°47'17" N, 070°08'25" W.</li> </ul>
Friendship Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Friendship Lobster Boat Race Committee.</li> <li>• Date: July 20, 2013.</li> <li>• Time: 9 a.m. to 3 p.m.</li> <li>• Location: The regulated area includes all waters of Friendship Harbor, Maine within the following points (NAD 83):  43°57'51" N, 069°20'46" W.  43°58'14" N, 069°19'53" W.  43°58'19" N, 069°20'01" W.  43°58'00" N, 069°20'46" W.</li> </ul>
Harpowell Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Harpswell Lobster Boat Race Committee.</li> <li>• Date: July 28, 2013.</li> <li>• Time: 11 a.m. to 4 p.m.</li> <li>• Location: The regulated area includes waters of Middle Bay near Harpswell, Maine within the following points (NAD 83):  43°44'15" N, 070°02'06" W.  43°44'59" N, 070°01'21" W.  43°44'51" N, 070°01'05" W.  43°44'06" N, 070°01'49" W.</li> </ul>
Moosabec Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Moosabec Boat Race Committee.</li> <li>• Date: July 29, 2013.</li> <li>• Time: 9 a.m. to 2 p.m.</li> <li>• Location: The regulated area includes all waters of Jonesport, Maine within the following points (NAD 83):  44°31'21" N, 067°36'44" W.  44°31'36" N, 067°36'47" W.  44°31'44" N, 067°35'36" W.  44°31'29" N, 067°35'33" W.</li> </ul>

## AUGUST

Eggemoggin Reach Regatta .....	<ul style="list-style-type: none"> <li>• Event Type: Wooden Boat Parade.</li> <li>• Sponsor: Rockport Marine, Inc. and Brookline Boat Yard.</li> <li>• Date: August 3, 2013.</li> <li>• Time: 11 a.m. to 7 p.m.</li> </ul>
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TABLE 1—(33 CFR 100.120)—Continued

Lake Champlain Dragon Boat Festival .....	<ul style="list-style-type: none"> <li>• Location: The regulated area includes all waters of Eggemoggin Reach and Jericho Bay in the vicinity of Naskeag Harbor, Maine within the following points (NAD 83):                44°15'16" N, 068°36'26" W.                44°12'41" N, 068°29'26" W.                44°07'38" N, 068°31'30" W.                44°12'54" N, 068°33'46" W.</li> <li>• Event Type: Rowing and Paddling Boat Race.</li> <li>• Sponsor: Dragonheart Vermont.</li> <li>• Date: August 4, 2013.</li> <li>• Time: 7 a.m. to 6 p.m.</li> </ul>
Southport Rowgatta Rowing and Paddling Boat Race. ....	<ul style="list-style-type: none"> <li>• Location: The regulated area includes all waters of Burlington Bay within the following points (NAD 83):                44°28'51" N, 073°13'28" W.                44°28'40" N, 073°13'40" W.                44°28'37" N, 073°13'29" W.                44°28'40" N, 073°13'17" W.</li> <li>• Event Type: Rowing and Paddling Boat Race.</li> <li>• Sponsor: Boothbay Region YMCA.</li> <li>• Date: August 10, 2013.</li> <li>• Time: 8 a.m. to 3 p.m.</li> </ul>
Winter Harbor Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Location: The regulated area includes all waters of Sheepscot Bay and Boothbay, on the shore side of Southport Island, Maine within the following points (NAD 83):                43°50'26" N, 069°39'10" W.                43°49'10" N, 069°38'35" W.                43°46'53" N, 069°39'06" W.                43°46'50" N, 069°39'32" W.                43°49'07" N, 069°41'43" W.                43°50'19" N, 069°41'14" W.                43°51'11" N, 069°40'06" W.</li> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Winter Harbor Chamber of Commerce.</li> <li>• Date: August 10, 2013.</li> <li>• Time: 9 a.m. to 3 p.m.</li> </ul>
Merritt Brackett Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Location: The regulated area includes all waters of Winter Harbor, Maine within the following points (NAD 83):                44°22'06" N, 068°05'13" W.                44°23'06" N, 068°05'08" W.                44°23'04" N, 068°04'37" W.                44°22'05" N, 068°04'44" W.</li> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Town of Bristol, Maine.</li> <li>• Date: August 11, 2013.</li> <li>• Time: 10 a.m. to 3 p.m.</li> </ul>
Multiple Sclerosis Regatta .....	<ul style="list-style-type: none"> <li>• Location: The regulated area includes all waters of Pemaquid Harbor, Maine within the following points (NAD 83):                43°52'16" N, 069°32'10" W.                43°52'41" N, 069°31'43" W.                43°52'35" N, 069°31'29" W.                43°52'09" N, 069°31'56" W.</li> <li>• Event Type: Regatta and Sailboat Race.</li> <li>• Sponsor: Maine Chapter, Multiple Sclerosis Society.</li> <li>• Date: August 17, 2013.</li> <li>• Time: 9 a.m. to 3 p.m.</li> </ul>
Multiple Sclerosis Harborfest Lobster Boat/Tugboat Races .....	<ul style="list-style-type: none"> <li>• Location: The regulated area for the start of the race includes all waters of Casco Bay, Maine in the vicinity of Peaks Island within the following points (NAD 83):                43°40'24" N, 070°14'20" W.                43°40'36" N, 070°13'56" W.                43°39'58" N, 070°13'21" W.                43°39'46" N, 070°13'51" W.</li> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Maine Chapter, National Multiple Sclerosis Society.</li> <li>• Date: August 18, 2013.</li> <li>• Time: 10 a.m. to 6 p.m.</li> <li>• Location: The regulated area includes all waters of Portland Harbor, Maine in the vicinity of Maine State Pier within the following points (NAD 83):                43°40'25" N, 070°14'21" W.                43°40'36" N, 070°13'56" W.                43°39'58" N, 070°13'21" W.                43°39'47" N, 070°13'51" W.</li> </ul>

TABLE 1—(33 CFR 100.120)—Continued

## SEPTEMBER

Pirates Festival Lobster Boat Races .....	<ul style="list-style-type: none"> <li>• Event Type: Power Boat Race.</li> <li>• Sponsor: Eastport Pirates Festival.</li> <li>• Date: September 8, 2013.</li> <li>• Time: 11 a.m. to 6 p.m.</li> <li>• Location: The regulated area includes all waters in the vicinity of Eastport Harbor, Maine within the following points (NAD 83): <ul style="list-style-type: none"> <li>44°54'14" N, 066°58'52" W.</li> <li>44°54'14" N, 068°58'56" W.</li> <li>44°54'24" N, 066°58'52" W.</li> <li>44°54'24" N, 066°58'56" W.</li> </ul> </li> </ul>
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TABLE 2—(33 CFR 165.171)

## MAY

Ride Into Summer (formerly listed as Hawgs, Pies, & Fireworks) .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Gardiner Maine Street.</li> <li>• Date: May 25, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of the Gardiner Waterfront, Gardiner, Maine in approximate position: <ul style="list-style-type: none"> <li>44°13'43" N, 069°46'04" W. (NAD 83).</li> </ul> </li> </ul>
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## JUNE

Rotary Waterfront Days Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Gardiner Rotary.</li> <li>• Date: June 22, 2013.</li> <li>• Time: 8 p.m. to 10 p.m.</li> <li>• Location: In the vicinity of the Gardiner Waterfront, Gardiner, Maine in approximate position: <ul style="list-style-type: none"> <li>44°13'52" N, 069°46'08" W. (NAD 83).</li> </ul> </li> </ul>
Windjammer Days Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Boothbay Harbor Region Chamber of Commerce.</li> <li>• Date: June 26, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of McFarland Island, Boothbay Harbor, Maine in approximate position: <ul style="list-style-type: none"> <li>43°50'38" N, 069°37'57" W. (NAD 83).</li> </ul> </li> </ul>
Jonesport 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Jonesport 4th of July Committee.</li> <li>• Date: June 29, 2013.</li> <li>• Time: 8:30 p.m. to 11 p.m.</li> <li>• Location: In the vicinity of Beals Island, Jonesport, Maine in approximate position: <ul style="list-style-type: none"> <li>44°31'18" N, 067°36'43" W. (NAD 83).</li> </ul> </li> </ul>

## JULY

Burlington Independence Day Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Firework Display.</li> <li>• Sponsor: City of Burlington, Vermont.</li> <li>• Date: July 3, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: From a barge in the vicinity of Burlington Harbor, Burlington, Vermont in approximate position: <ul style="list-style-type: none"> <li>44°28'31" N, 073°13'31" W. (NAD 83).</li> </ul> </li> </ul>
Camden 4th of July Fireworks (Formerly Camden 3rd of July Fireworks).	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Penobscot Bay Regional Chamber of Commerce (Formerly Camden, Rockport, Lincolnville Chamber of Commerce).</li> <li>• Date: July 4, 2013.</li> <li>• Time: 8:15 p.m. to 10:45 p.m.</li> <li>• Location: In the vicinity of Camden Harbor, Maine in approximate position: <ul style="list-style-type: none"> <li>44°12'32" N, 069°02'58" W. (NAD 83).</li> </ul> </li> </ul>
Bangor 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Bangor 4th of July Fireworks.</li> <li>• Date: July 4, 2013.</li> <li>• Time: 8:30 p.m. to 11 p.m.</li> <li>• Location: In the vicinity of the Bangor Waterfront, Bangor, Maine in approximate position: <ul style="list-style-type: none"> <li>44°47'27" N, 068°46'31" W. (NAD 83).</li> </ul> </li> </ul>

TABLE 2—(33 CFR 165.171)—Continued

Bar Harbor 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Bar Harbor Chamber of Commerce.</li> <li>• Date: July 4, 2013.</li> <li>• Rain date: July 5, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Bar Harbor Town Pier, Bar Harbor, Maine in approximate position: 44°23'31" N, 068°12'15" W. (NAD 83).</li> </ul>
Boothbay Harbor 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Town of Boothbay Harbor.</li> <li>• Date: July 4, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of McFarland Island, Boothbay Harbor, Maine in approximate position: 43°50'38" N, 069°37'57" W. (NAD 83).</li> </ul>
Colchester 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Town of Colchester, Recreation Department.</li> <li>• Date: July 4, 2013.</li> <li>• Rain Date: July 5, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Bayside Beach and Mallets Bay in Colchester, Vermont in approximate position: 44°32'44" N, 073°13'10" W. (NAD 83).</li> </ul>
Eastport 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Eastport 4th of July Committee.</li> <li>• Date: July 4, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: From the Waterfront Public Pier in Eastport, Maine in approximate position: 44°54'25" N, 066°58'55" W. (NAD 83).</li> </ul>
Portland Harbor 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Department of Parks and Recreation, Portland, Maine.</li> <li>• Date: July 4, 2013.</li> <li>• Rain date: July 5, 2013.</li> <li>• Time: 8:30 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of East End Beach, Portland, Maine in approximate position: 43°40'16" N, 070°14'44" W. (NAD 83).</li> </ul>
Stonington 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Deer Isle—Stonington Chamber of Commerce.</li> <li>• Date: July 4, 2013.</li> <li>• Rain Date: July 5, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Two Bush Island, Stonington, Maine in approximate position: 44°08'57" N, 068°39'54" W. (NAD 83).</li> </ul>
Ellis Short Sand Park Trustee Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: William Burnham.</li> <li>• Date: July 5, 2013.</li> <li>• Time: 8:30 p.m. to 11:30 p.m.</li> <li>• Location: In the vicinity of York Beach, Maine in approximate position: 43°10'27" N, 070°36'25" W. (NAD 83).</li> </ul>
Shelburne Sprint Triathlon .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Race Vermont.</li> <li>• Dates: July 6, 2013 and August 3&amp;18, 2013.</li> <li>• Time: 7 a.m. to 10 a.m.</li> <li>• Location: The regulated area includes all waters of Lake Champlain in the vicinity of Shelburne Beach in Shelburne, Vermont within a 400 yard radius of the following point (NAD 83): 44°21'45" N, 075°15'58" W.</li> </ul>
Vinalhaven 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Firework Display.</li> <li>• Sponsor: Vinalhaven 4th of July Committee.</li> <li>• Date: July 6, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Grime's Park, Vinalhaven, Maine in approximate position: 44°02'34" N, 068°50'26" W. (NAD 83).</li> </ul>
Main Street Heritage Days 4th of July Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Main Street Inc.</li> <li>• Date: July 7, 2013.</li> <li>• Time: 8:15 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Reed and Reed Boat Yard, Woolwich, Maine in approximate position:</li> </ul>

TABLE 2—(33 CFR 165.171)—Continued

St. Albans Day Fireworks .....	<p>43°54'56" N, 069°48'16" W. (NAD 83).</p> <ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: St. Albans Area Chamber of Commerce.</li> <li>• Date: July 9, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: From the St. Albans Bay dock in St. Albans Bay, Vermont in approximate position: 44°48'25" N 073° 08'23" W. (NAD 83).</li> </ul>
Peaks to Portland Swim .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Cumberland County YMCA.</li> <li>• Date: July 13, 2013.</li> <li>• Time: 9 a.m. to 12 p.m.</li> <li>• Location: The regulated area includes all waters of Portland Harbor between Peaks Island and East End Beach in Portland, Maine within the following points (NAD 83): 43°39'20" N 070°11'58" W. 43°39'45" N 070°13'19" W. 43°40'11" N 070°14'13" W. 43°40'08" N 070°14'29" W. 43°40'00" N 070°14'23" W. 43°39'34" N 070°13'31" W. 43°39'13" N 070°11'59" W.</li> </ul>
St. George Days Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks.</li> <li>• Sponsor: Town of St. George.</li> <li>• Date: July 20, 2013.</li> <li>• Time: 8:30 p.m. to 10:30 p.m.</li> <li>• Location: The regulated area includes all waters of Inner Tenants Harbor, ME, in approximate position (NAD 83): 43°57'41.37" N, 069°12'45" W.</li> </ul>
Richmond Days Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Town of Richmond, Maine.</li> <li>• Date: July 27, 2013.</li> <li>• Time: 9:15 p.m. to 9:30 p.m.</li> <li>• Location: From a barge in the vicinity of the inner harbor, Tenants Harbor, Maine in approximate position: 44°08'42" N, 068°27'06" W. (NAD83).</li> </ul>
Friendship Days Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Town of Friendship.</li> <li>• Date: July 27, 2013.</li> <li>• Time: 9 p.m. to 9:30 p.m.</li> <li>• Location: In the vicinity of the Town Pier, Friendship Harbor, Maine in approximate position: 43°58'23" N, 069°20'12" W. (NAD83).</li> </ul>
Bucksport Festival and Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Bucksport Bay Area Chamber of Commerce.</li> <li>• Date: July 27, 2013.</li> <li>• Time: 9:15 p.m. to 10 p.m.</li> <li>• Location: In the vicinity of the Verona Island Boat Ramp, Verona, Maine, in approximate position: 44°34'9" N, 068°47'28" W (NAD83).</li> </ul>
Colchester Triathlon .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Colchester Parks and Recreation Department.</li> <li>• Date: July 28, 2013.</li> <li>• Time: 9 a.m. to 9:45 a.m.</li> <li>• Location: The regulated area includes all waters of Malletts Bay on Lake Champlain, Vermont within the following points (NAD 83): 44°32'18" N 073°12'35" W. 44°32'28" N 073°12'56" W. 44°32'57" N 073°12'38" W.</li> </ul>

## AUGUST

Sprucewold Cabbage Island Swim .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Sprucewold Association.</li> <li>• Date: August 10, 2013.</li> <li>• Time: 1 p.m. to 6 p.m.</li> <li>• Location: The regulated area includes all waters of Linekin Bay between Cabbage Island and Sprucewold Beach in Boothbay Harbor, Maine within the following points (NAD 83): 43°50'37" N 069°36'23" W. 43°50'37" N 069°36'59" W. 43°50'16" N 069°36'46" W. 43°50'22" N 069°36'21" W.</li> </ul>
Westerlund's Landing Party Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> </ul>

TABLE 2—(33 CFR 165.171)—Continued

	<ul style="list-style-type: none"> <li>• Sponsor: Portside Marina.</li> <li>• Date: August 3, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Westerlund’s Landing in South Gardiner, Maine in approximate position: 44°10’19” N, 069°45’24” W. (NAD 83).</li> </ul>
Y-Tri Triathlon .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Plattsburgh YMCA.</li> <li>• Date: August 3, 2013.</li> <li>• Time: 8:30 a.m. to 10 a.m.</li> <li>• Location: The regulated area includes all waters of Treadwell Bay on Lake Champlain in the vicinity of Point Au Roche State Park, Plattsburgh, New York within the following points (NAD 83): 44°46’30” N 073°23’26” W. 44°46’17” N 073°23’26” W. 44°46’17” N 073°23’46” W. 44°46’29” N 073°23’46” W.</li> </ul>
York Beach Fire Department Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: York Beach Fire Department.</li> <li>• Date: August 4, 2013.</li> <li>• Time: 8:30 p.m. to 11:30 p.m.</li> <li>• Location: In the vicinity of Short Sand Cove in York, Maine in approximate position: 43°10’27” N, 070°36’25” W. (NAD 83).</li> </ul>
Rockland Breakwater Swim .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Pen-Bay Masters.</li> <li>• Date: August 31, 2013.</li> <li>• Time: 7:30 a.m. to 1:30 p.m.</li> <li>• Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of Jameson Point within the following points (NAD 83): 44°06’16” N 069°04’39” W. 44°06’13” N 069°04’36” W. 44°06’12” N 069°04’43” W. 44°06’17” N 069°04’44” W. 44°06’18” N 069°04’40” W.</li> </ul>
Tri for Preservation .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Tri-Maine Productions.</li> <li>• Date: August 18, 2013.</li> <li>• Time: 6:30 a.m. to 10 a.m.</li> <li>• Location: In the vicinity of Crescent Beach State Park in Cape Elizabeth, Maine in approximate position: 43°33’46” N 070°13’48” W. 43°33’41” N 070°13’46” W. 43°33’44” N 070°13’40” W. 43°33’47” N 070°13’46” W.</li> </ul>
Windjammer Weekend Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Town of Camden, Maine.</li> <li>• Date: August 30, 2013.</li> <li>• Rain date: September 1, 2013.</li> <li>• Time: 8 p.m. to 9:30 p.m.</li> <li>• Location: From a barge in the vicinity of Northeast Point, Camden Harbor, Maine in approximate position: 44°12’10” N, 069°03’11” W. (NAD 83).</li> </ul>

**SEPTEMBER**

Eastport Pirate Festival Fireworks .....	<ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Eastport Pirate Festival.</li> <li>• Date: September 7, 2013.</li> <li>• Time: 7 p.m. to 10:00 p.m.</li> <li>• Location: From the Waterfront Public Pier in Eastport, Maine in approximate position: 44°54’17” N, 066°58’58” W. (NAD 83).</li> </ul>
The Lobsterman Triathlon .....	<ul style="list-style-type: none"> <li>• Event Type: Swim Event.</li> <li>• Sponsor: Tri-Maine Productions.</li> <li>• Date: September 14, 2013.</li> <li>• Time: 7 a.m. to 11:00 a.m.</li> <li>• Location: The regulated area includes all waters in the vicinity of Winslow Park in South Freeport, Maine within the following points (NAD 83): 43°47’59” N 070°06’56” W. 43°47’44” N 070°06’56” W.</li> </ul>

TABLE 2—(33 CFR 165.171)—Continued

Eliot Festival Day Fireworks .....	<p>43°47'44" N 070°07'27" W. 43°47'57" N 070°07'27" W.</p> <ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Eliot Festival Day Committee.</li> <li>• Date: September 27, 2013.</li> <li>• Rain date: September 29, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Eliot Town Boat Launch, Eliot, Maine in approximate position: 43°08'56" N, 070°49'52" W. (NAD 83).</li> </ul>
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For events where the date is different from the dates previously published for that event, new Temporary Rules may be issued to enforce limited access areas for the marine event. The Coast Guard may patrol each event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF-FM (156.8 MHz) by the call sign "PATCOM." Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the Captain of the Port, Sector Northern New England. For information about regulations and restrictions for waterway use during the effective periods of these events, please refer to 33 CFR 100.120 and 33 CFR 165.171.

This notice is issued under authority of 33 CFR 100.120, 33 CFR 165.171, and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: May 24, 2013.

**B.S. Gilda,**

*Captain, U. S. Coast Guard, Captain of the Port Sector Northern New England.*

[FR Doc. 2013-13907 Filed 6-11-13; 8:45 am]

BILLING CODE 9110-04-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2012-0921; FRL-9386-8]

**1,3-Propanediol; Exemptions From the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes exemptions from the requirement of a tolerance for residues of 1,3-propanediol (CAS Reg. No. 504-63-2) when used as an inert ingredient solvent, co-solvent, diluent, or freeze-point depressant in pesticide formulations applied to growing crops and to raw agricultural crops after harvest and in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. DuPont Tate & Lyle BioProducts submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance. These regulations eliminate the need to establish a maximum permissible level for residues of 1,3-propanediol.

**DATES:** This regulation is effective June 12, 2013. Objections and requests for hearings must be received on or before August 12, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0921, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** David Lieu, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-0079; email address: [lieu.david@epa.gov](mailto:lieu.david@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0921 in the subject line on