

the market cannot be legally marketed without approval.

To address this situation, FDA is revising CPG 440.100 to make clear that unapproved new drugs introduced onto the market after September 19, 2011 are subject to enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in CPG 440.100 for unapproved new drugs marketed prior to September 19, 2011. The revision to CPG 440.100 excludes from the enforcement priorities set forth in the guidance the manufacture and marketing of newly introduced unapproved drugs.

This guidance represents the Agency's current thinking on its enforcement priorities with respect to new drugs marketed without approved new drug applications or abbreviated new drug applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.
ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS FORT WORTH (LCS 3) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective September 21, 2011 and is applicable beginning September 8, 2011.

FOR FURTHER INFORMATION CONTACT: Lieutenant Jaewon Choi, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE., Suite 3000, Washington Navy Yard, DC 20374-5066, telephone number: 202-685-5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS FORT WORTH (LCS 3) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the height of the forward masthead light above the hull; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light, and the horizontal separation between the forward and after masthead

lights; Annex I, paragraph 2(i)iii, pertaining to the spacing of the three lights in the task light array; Rule 27, paragraph (b)i, pertaining to the verticality of the three all-round task lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

For the reasons set forth in the preamble, the Navy amends part 706 of title 32 of the CFR as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

- 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

- 2. Section 706.2 is amended as follows:

- A. In Table One, add, in alpha numerical order by vessel number, an entry for USS FORT WORTH (LCS 3);
- B. In Table Four, under paragraph 22 add, in alphanumerical order by vessel number, an entry for USS FORT WORTH (LCS 3);
- C. In Table Four, under paragraph 23 add, in alphanumerical order by vessel number, an entry for USS FORT WORTH (LCS 3); and
- D. In Table Five add, in alpha numerical order by vessel number, an entry for USS FORT WORTH (LCS 3).

The additions read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE ONE

Vessel	Number	Distance in meters of forward masthead light below minimum required height. § 2(a)(i) Annex I
USS FORT WORTH	LCS 3	5.965

* * * * *

22. * * *

TABLE FOUR

Vessel	Number	Vertical separation of the task light array is not equally spaced, the separation between the middle and lower task light exceed the separation between the upper and middle light by:
USS FORT WORTH	LCS 3	0.41 meter

23. * * *

Vessel	Number	Verticality of lights, when viewed directly from the port or starboard, the lower task light is out of alignment with the upper and middle task light in meters by:	Verticality of lights, when viewed directly from the bow or stern, the lower task light is out of alignment with the upper and middle task light in meters by:
USS FORT WORTH	LCS 3		0.21

* * * * *

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. annex I, sec. 3(a)	After mast-head light less than 1/2 ship's length aft of forward masthead light. annex I, sec. 3(a)	Percentage horizontal separation attained
USS FORT WORTH.	LCS 3		X	X	23

Approved: September 9, 2011.

M. Robb Hyde,

Commander, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).

Dated: September 13, 2011.

J.M. Beal,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0575]

RIN 1625-AA00

Safety Zone; Swim Around Charleston, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone during the Swim Around Charleston, a swimming race occurring on waters of the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina. The Swim Around Charleston is scheduled to take place on Sunday, October 23, 2011. The temporary safety zone is necessary for the safety of the swimmers, 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 Charleston or a designated representative.

DATES: This rule is effective from 10 a.m. until 4 p.m. on October 23, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2011-0575 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0575 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 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 e-mail Ensign John R. Santorum, Sector Charleston Office of Waterways Management, Coast Guard; telephone 843-740-3184, e-mail John.R.Santorum@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On July 1, 2011, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Swim Around Charleston, Charleston, SC in the **Federal Register** (76 FR 38586). We received no comments on the proposed rule. No public meeting was requested, and none was held.

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, 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to ensure the safety of the swimmers, participant vessels, spectators, and the general public during the Swim Around Charleston.

Discussion of Comments and Changes

The Coast Guard did not receive any comments to the proposed rule, and no changes were made to the regulatory text.

Discussion of Rule

On Sunday, October 23, 2011, the Swim Around Charleston is scheduled to take place on the waters of the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina. The Swim Around Charleston will consist of a 10-mile swim that starts at Remley's Point on the Wando River, crosses the main shipping channel of Charleston Harbor, and finishes at the General William B. Westmoreland Bridge on the Ashley River.

This rule establishes a temporary moving safety zone of a 75-yard radius around the Swim Around Charleston participant vessels that are officially associated with the swim on the waters of the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina. The temporary safety zone will be enforced from 10 a.m. until 4 p.m. on

October 23, 2011. 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 Charleston or a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within the safety zone may contact the Captain of the Port Charleston by telephone at 843-740-7050, or a designated representative via VHF radio on channel 16, to request authorization.

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.

Executive Order 12866 and Executive Order 13563

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, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. 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 only be enforced for a total of six hours; (2) the safety zone will move with the participant vessels so that once the swimmers clear a portion of the waterway, the safety zone will no longer be enforced in that portion of the waterway; (3) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) 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.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit