

MedWatch if they experience any adverse events with this device.

- The anticipated number of device uses prior to failure.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is exempt from premarket notification requirements. Persons who intend to market this type of device need not submit to FDA a premarket notification, prior to marketing the device, which contains information about the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. DEN100024: De Novo Request per 513(f)(2) from Ecobrand, Ltd., dated September 8, 2010.
2. DEN130019: De Novo Request per 513(f)(2) from Tecnimed S.r.l., dated February 14, 2013.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 2. Add § 882.5894 to subpart F to read as follows:

§ 882.5894 Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites.

(a) *Identification.* A limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites is a device intended to alleviate skin reactions associated with insect bites via cutaneous, piezoelectric stimulation at the local site of the bite.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate testing to characterize the electrical output specifications of the device (*i.e.*, total charge delivered, maximum instantaneous output current, maximum instantaneous output voltage, pulse duration, charge density) must be conducted.

(2) Mechanical bench testing must demonstrate that the device will withstand the labeled number duration of uses.

(3) All elements of the device that may contact the patient must be assessed to be biocompatible.

(4) Labeling must include:

(i) Validated instructions which addresses the following:

(A) Identification of areas of the body which are appropriate and not appropriate for contact with the device.

(B) Whether use of the device in conjunction with flammable materials (*e.g.*, insect repellent) is appropriate.

(C) Use of the device on or near implanted devices.

(D) How to identify the correct type of skin condition.

(ii) Technical parameters of the device (maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration).

(iii) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.

(iv) The anticipated number of device uses prior to failure.

Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06499 Filed 3–20–15; 8:45 am]

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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, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS JOHN WARNER (SSN 785) 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 March 23, 2015 and is applicable beginning January 28, 2015.

FOR FURTHER INFORMATION CONTACT:

Commander Theron R. Korsak, (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 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 JOHN WARNER (SSN 785) 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 vertical placement of the masthead light; Annex I, paragraph 2(f)(i), pertaining to Virginia class submarine masthead light location below the submarine identification lights; Annex I, paragraph 2(k), pertaining to the vertical separation of the anchor lights and vertical placement of the forward anchor light above the hull; Rule 30(a) and Rule 21(e), pertaining to arc of visibility of the forward and after anchor lights; Annex I, paragraph 3(b), pertaining to the location of the sidelights; and Rule 21(c), pertaining to the location and arc of visibility of the sternlight. 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), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations 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 by:

■ a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS JOHN WARNER (SSN 785);

■ b. In Table Three, adding, in alpha numerical order, by vessel number, an entry for USS JOHN WARNER (SSN 785);

■ c. In Table Four, under paragraph 25, adding, in alpha numerical order, by vessel number, an entry for USS JOHN WARNER (SSN 785); and

■ d. In Table Four, paragraph 26, adding, in alpha numerical order, by vessel number, an entry for USS JOHN WARNER (SSN 785).

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 JOHN WARNER	SSN 785	2.76

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TABLE THREE

Vessel	Number	Masthead lights arc of visibility; rule 21(a)	Side lights arc of visibility; rule 21(b)	Stern light arc of visibility; rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) annex 1	Stern light, distance forward of stern in meters; rule 21(c)	Forward anchor light, height above hull in meters; 2(K) annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) annex 1
USS JOHN WARNER.	SSN 785	206.4°	4.37	11.05	2.8	0.30 below.

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25. * * *

TABLE FOUR

Vessel	Number	Distance in meters of masthead light below the submarine identification lights
USS JOHN WARNER	SSN 785	0.81

26. * * *

Obstruction angle relative to ship's heading		Forward Anchor Light	Aft Anchor Light
Vessel	Number		
USS JOHN WARNER	SSN 785	172° to 188°	359° to 1°

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Approved: January 28, 2015.

A.B. Fischer,*Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).*

Dated: March 11, 2015.

N.A. Hagerty-Ford,*Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.*

[FR Doc. 2015-06298 Filed 3-20-15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG-2015-0062]

Special Local Regulation; Annual Marine Events on the Colorado River, Between Davis Dam (Bullhead City, Arizona) and Headgate Dam (Parker, Arizona) Within the San Diego Captain of the Port Zone**AGENCY:** Coast Guard, DHS.**ACTION:** Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the 2015 Lake Havasu Desert Storm marine event special local regulations from 8 a.m. through 3 p.m. on April 25, 2015. This annual marine event occurs on the navigable waters of the Colorado River in Lake Havasu, Arizona. This action is necessary to provide for the safety of the participants, crew, spectators, safety vessels, and general users of the waterway. During the enforcement period, persons and vessels

are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1102, Table 1, Item 4 will be enforced from 8 a.m. through 3 p.m. on April 25, 2015. If the event is delayed by inclement weather, these regulations will also be enforced from 8 a.m. through 3 p.m. on April 26, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email Petty Officer Nick Bateman, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619-278-7656, *D11-PF-MarineEventsSanDiego@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local Regulations in Lake Havasu for the 2015 Desert Storm Shootout in 33 CFR 100.1102, Table 1, Item 4 from 8 a.m. through 3 p.m. on April 25, 2015. If the event is delayed by inclement weather, these regulations will also be enforced from 8 a.m. through 3 p.m. on April 26, 2015.

Under provisions of 33 CFR 100.1102, persons and vessels are prohibited from entering into, transiting through, or anchoring within the regulated area, unless authorized by the Coast Guard Captain of the Port or his designated representative. Persons or vessels desiring to enter into or pass through the special local regulations may request permission from the Captain of the Port or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the Captain of the Port or his designated representative. Spectator vessels may safely transit outside the regulated area but may not anchor,

block, loiter, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or Local law enforcement agencies in enforcing this regulation.

This document is issued under authority of 33 CFR 100.1102 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: March 6, 2015.

J.A. Janszen,*Commander, U.S. Coast Guard, Acting, Captain of the Port San Diego.*

[FR Doc. 2015-06603 Filed 3-20-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG-2015-0129]

RIN 1625-AA00

Safety Zone, Delaware River; Marcus Hook, PA**AGENCY:** Coast Guard, DHS.