

in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

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

2. Section 866.1 is amended by adding paragraph (e) to read as follows:

§ 866.1 Scope.

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(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh.guidance.html>.

3. Section 866.1645 is added to subpart B to read as follows:

§ 866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system.

(a) *Identification.* A fully automated short-term incubation cycle antimicrobial susceptibility system is a device that incorporates concentrations of antimicrobial agents into a system for the purpose of determining in vitro susceptibility of bacterial pathogens isolated from clinical specimens. Test

results obtained from short-term (less than 16 hours) incubation are used to determine the antimicrobial agent of choice to treat bacterial diseases.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA."

Dated: January 9, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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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 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 (Admiralty and Maritime Law) has determined that USS HOWARD (DDG 83) 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.

EFFECTIVE DATE: August 8, 2002.

FOR FURTHER INFORMATION CONTACT: Captain Richard T. Evans, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (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 Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS HOWARD (DDG 83) 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 3(a) pertaining to the location of the forward masthead light in the forward quarter of the vessel, and the horizontal distance between the forward and after masthead lights; and Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions. The Deputy Assistant Judge Advocate General (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.

Accordingly, 32 CFR part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

2. Table Four, Paragraph 16 of § 706.2 is amended by revising the following entry for USS HOWARD:

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

* * * * *

Vessel					Number	Obstruction angle relative ship's headings
* * * * *					*	*
USS HOWARD					DDG 83	109.11 thru 112.50°
* * * * *					*	*

3. Table Five of § 706.2 is amended by revising the following entry for USS HOWARD:

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

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TABLE FIVE

Vessel	No.	Masthead lights not over all other lights and obstructions. annex I, sec. 2(f)	Forward mast-head 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 mast-head light. Annex I, sec. 3(a)	Percentage horizontal separation attained
USS HOWARD	DDG 83	X	X	X	14.6
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Dated: August 8, 2002.

Richard T. Evans,

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

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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 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 (Admiralty and Maritime Law) has determined that USS PREBLE (DDG 88) 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.

EFFECTIVE DATE: May 31, 2002.

FOR FURTHER INFORMATION CONTACT:

Captain Richard T. Evans, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (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 Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS PREBLE (DDG 88) 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 3(a) pertaining to the location of the forward masthead light in the forward quarter of the vessel, and the horizontal distance between the forward and after masthead lights; Annex I, paragraph 3(c), pertaining to placement of task lights not less than two meters from the fore and aft centerline of the ship in the athwartship direction; Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions; and Annex I, paragraph 2(f)(ii), pertaining to the

vertical placement of task lights. The Deputy Assistant Judge Advocate General (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.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

2. Table Four, Paragraph 15 of § 706.2 is amended by adding, in numerical order, the following entry for USS PREBLE:

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

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Vessel	Number	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
USS PREBLE	DDG 88	1.93 meters
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