

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 16, 610, 640, 812, 814, 822, and 860**

[Docket No. FDA-2008-N-0423]

FDA Regulations; Technical Amendment; Correction**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of Monday, August 25, 2008 (73 FR 49941). The final rule made technical amendments to several FDA regulations. The document was published with two inaccurate citations in the first paragraph of the Background Section under Supplementary Information. This document corrects that error.

DATES: September 19, 2008.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In FR Doc. E8-19654, appearing on page 49941 in the **Federal Register** of Monday, August 25, 2008 (73 FR 49941), the following correction is made:

On page 49941, in the first paragraph of the Background section under Supplementary Information, "21 CFR 610.51" is corrected to read as "21 CFR 610.53" and "21 CFR 640.53" is corrected to read as "21 CFR 640.51".

Dated: September 15, 2008.

Jeffrey Shuren,*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-21966 Filed 9-18-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF STATE**22 CFR Part 121**

[Public Notice: 6364]

Amendment to the International Traffic in Arms Regulations: U.S. Munitions List Interpretation**AGENCY:** Department of State.**ACTION:** Final rule.

SUMMARY: The Department of State is amending the International Traffic in

Arms Regulations (ITAR) to clarify that certain anti-tumor drugs are not within the definition of "chemical agents."

DATES: *Effective Date:* This rule is effective September 19, 2008.

ADDRESSES: Interested parties may submit comments at any time by any of the following methods:

- *E-mail:*

DDTCResponseTeam@state.gov with an appropriate subject line.

- *Mail:* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, 12th Floor, SA-1, Washington, DC 20522-0112.

- *Fax:* 202-261-8199.

Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at: *http://www.regulations.gov/index.cfm*.

FOR FURTHER INFORMATION CONTACT: Lisa Wenger, Office of Defense Trade Controls Policy, Department of State; Telephone 202-663-2171 or FAX 202-261-8199; *e-mail:* *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change.

SUPPLEMENTARY INFORMATION: In this regulatory change, we clarify that certain anti-tumor drugs are not considered defense articles under this subchapter; however, the know-how for production of nitrogen mustards or their salts is specifically retained on the U.S. Munitions List.

Regulatory Analysis and Notices*Administrative Procedure Act*

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures contained in 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the provisions of section 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604).

Unfunded Mandates Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not 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. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. Executive Order 12372, regarding intergovernmental consultation on Federal programs and activities, does not apply to this amendment.

Executive Order 12866

This amendment is exempt from review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports, U.S. Munitions List.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 121 is amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

■ 1. The authority citation for part 121 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub.L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub.L. 105-261, 112 Stat. 1920.

■ 2. In § 121.1, paragraph (c) Category XIV is amended by adding NOTE 5 to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

(c) * * *

* * * * *

Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment

* * * * *

Note 5: Pharmacological formulations containing nitrogen mustards and certain reference standards for these drugs are not considered to be chemical agents and are licensed by the Department of Commerce when:

(1) The drug is in the form of a final medical product; or

(2) The reference standard contains salts of HN2 [bis(2-chloroethyl) methylamine], the quantity to be shipped is 150 milligrams or less, and individual shipments do not exceed twelve per calendar year per end user.

Technical data for the production of HN1 [bis(2-chloroethyl)ethylamine]; HN2 [bis(2-chloroethyl)methylamine], HN3 [tris(2-chloroethyl)amine]; or salts of these, such as tris (2-chloroethyl)amine hydrochloride, remains controlled under this Category.

* * * * *

Dated: September 3, 2008.

Frank J. Ruggiero,

Acting Assistant Secretary for Political-Military Affairs, Department of State.

[FR Doc. E8-21832 Filed 9-18-08; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2008-0915]

RIN 1625-AA00

Temporary Safety Zone; Wreckage of the M/V NEW CARISSA, Pacific Ocean 3 Nautical Miles North of the Entrance to Coos Bay, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Pacific Ocean encompassed in the 1,000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 nautical miles north of the entrance to Coos Bay, Oregon. The Captain of the Port Portland is taking this action to safeguard individuals and vessels involved in a salvage operation involving the M/V NEW CARISSA. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative.

DATES: This regulation is effective from 12:01 p.m. August 31, 2008, to 12 p.m. September 30, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-0915 and are available online at www.regulations.gov. They are also available for inspection or copying at

two locations: 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, and Coast Guard Sector Portland, 6767 N. Basin Ave., Portland, OR 97217, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call MST1 Jaime Sayers, Waterways Management, at (503) 240-9311. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because immediate action is necessary to protect human safety of those involved in the salvage operations of the NEW CARISSA. Such action will be taken by limiting public access to the salvage area. For those same reasons under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

This rule is related to the safety zone published in the **Federal Register** on June 27, 2008 (73 FR 36433). In that rule the Coast Guard established a temporary safety zone on the waters of the Pacific Ocean encompassed in the 1,000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 nautical miles north of the entrance to Coos Bay, Oregon. The Captain of the Port Portland took that action to safeguard individuals and vessels involved in a salvage operation involving the wreck of the M/V NEW CARISSA.

With this rule, for the same reasons as stated above, the Coast Guard is establishing a safety zone in the same area because individuals involved in the

salvage operation of the NEW CARISSA have not completed their task.

Entry into this safety zone is prohibited from 12:01 p.m. August 31, 2008 to 12 p.m. September 30, 2008, unless authorized by the Captain of the Port or his designated representative. This safety zone will be enforced by representatives of the Captain of the Port Portland. The Captain of the Port may be assisted by other federal, state, and local agencies.

Discussion of Rule

This rule, for safety concerns, will control vessels, personnel, and individual movements on the waters of the Pacific Ocean encompassed in the 1,000 yard radius surrounding the wreckage of the M/V NEW CARISSA located 3 nautical miles north of the entrance to Coos Bay, Oregon. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representative. Coast Guard Personnel and local law enforcement will enforce this safety zone.

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.

Regulatory Planning and Review

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the safety zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), 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 organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.