

**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**

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](mailto: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](mailto: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) \* \* \*  
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**Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment**

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**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