

time. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes dispenses, imports or exports remifentanyl or who engages in research or conducts instructional activities with remifentanyl, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* Remifentanyl must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (a), (c), and (d), 1301.73, 1301.74, 1301.75 (b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, remifentanyl which is distributed on and after November 5, 1996 shall comply with the requirements of §§ 1302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for remifentanyl are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing remifentanyl are required to take inventories pursuant to §§ 1304.04 and 1304.11–1304.19 of Title 21 of the Code of Federal Regulations.

6. *Records.* All registrants must keep records pursuant to §§ 1304.04 and 1304.21–1304.29 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants are required to file reports pursuant to §§ 1304.34–1304.37 of Title 21 of the Code of Federal Regulations.

8. *Order Forms.* Each distribution of remifentanyl requires the use of an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* As remifentanyl has been approved by the FDA for use in medical treatment, the drug may be dispensed by prescription. Prescriptions for remifentanyl are to be issued pursuant to §§ 1306.01–1306.07 and 1306.11–1306.15 of Title 21 of the Code of Federal Regulations.

10. *Importation and Exportation.* All importation and exportation of remifentanyl shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with remifentanyl not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this order to place remifentanyl into Schedule II of the CSA is a formal rulemaking “on the

record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Remifentanyl is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule II of the CSA. Remifentanyl, a potent opioid drug, can produce drug dependence of the morphine type. This drug is likely to be diverted and abused if access to it is not closely monitored. The labeled indication for use of remifentanyl is to provide analgesia during the induction and maintenance of general anesthesia. It is to be administered by trained professionals in monitored anesthesia care settings. Schedule II narcotic control will provide the necessary drug monitoring. Small-business entities which are likely to handle this drug maintain a Schedule II narcotic registration with the DEA. This rule will allow these entities to have access to a new pharmaceutical product.

This rule 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 E.O. 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by Section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.12 is amended by redesignating the existing paragraph (c)(26) as (c)(27) and adding a new paragraph (c)(26) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(26) Remifentanyl9739

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Dated: October 26, 1996.

James S. Milford, Jr.,

Acting Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96-28294 Filed 11-4-96; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 2465]

Removal of Commercial Communications Satellites and Hot Section Technology From State's USML for Transfer to Commerce's CCL

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) by removing from the U.S. Munitions List (USML), for transfer to the Department of Commerce's Commerce Control List, hot-section technologies associated with commercial aircraft engines and commercial communications satellites.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: William Lowell, Director, Office of Defense Trade Controls, Department of State, Telephone (703) 812-2567 or FAX (703) 875-6647 ATTN: Regulatory Change, Commercial Communications Satellites and Commercial Hot Section Technologies.

SUPPLEMENTARY INFORMATION: On March 14, 1996, the Administration announced a decision concerning commercial aircraft engine hot section technologies and commercial communications satellites. The decision has several key features. First, commercial aircraft engine hot section technologies will be controlled on the Commerce Control List (CCL) of dual-use items that are licensed by Commerce. Commercial

communications satellites will be controlled on the dual-use list, as well, even if they include individual munitions list components or technologies; in all other cases, munitions list components or technologies, themselves, will continue to be controlled on the U.S. Munitions List, subject to State Department licensing. Second, new control procedures and regulations have been developed for the Commerce control list that will provide for strong national security and foreign policy controls to all destinations and end users worldwide for these items. Enhanced Interagency review of CCL licenses for these items has been established. This decision does not result in the decontrol of any of these items. The Administration's decision only serves to provide clarification from which agency exporters must obtain licenses for exports of commercial aircraft engine hot section technology and commercial communications satellites by removing these items from the U.S. Munitions List for transfer to the Commerce Control List.

In carrying out this directive, Categories VIII, XIII and XV of the U.S. Munitions List are amended.

This amendment involves a foreign affairs function of the United States. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. It is also not subject to 5 U.S.C. 553 and 554, and does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, Commercial Communications Satellites and Commercial Hot Section Technologies, Room 200, SA-6, Washington, D.C. 2052-0602.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter 1, subchapter M, is amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

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

Authority: Sec. 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.

2. In § 121.1 Category VIII is amended by revising paragraphs (f) and (i); Category XIII is amended by adding

immediately before the Note, a new paragraph (b)(1)(x); and Category XV is amended by revising paragraphs (a), (c), (e) and (f) and by adding a paragraph (g) to read as follows:

§ 121.1 General. The United States Munitions List.

Category VIII—Aircraft and Associated Equipment

* * * * *

(f) Developmental aircraft, engines, and components thereof specifically designed, modified, or equipped for military uses or purposes, or developed principally with U.S. Department of Defense funding, excluding such aircraft, engines, and components subject to the jurisdiction of the Department of Commerce.

Note: Developmental aircraft, engines, and components thereof, having no commercial application at the time of this amendment and which have been specifically designed for military uses or purposes, or developed principally with U.S. Department of Defense funding, will be considered eligible for a CCL license when actually applied to a commercial aircraft or commercial aircraft engine program. Exporters may seek to establish commercial application either on a case-by-case basis through submission of documentation demonstrating application to a commercial program in requesting an export license application from Commerce in respect of a specific export or, in the case of use for broad categories of aircraft, engines, or components, a commodity jurisdiction from State.

(g) * * *

(h) * * *

(i) Technical data (as defined in § 120.10) and defense services (as defined in § 120.9) directly related to the defense articles enumerated in paragraphs (a) through (h) of this category (see § 125.4 for exemptions), except for hot section technical data associated with commercial aircraft engines. Technical data directly related to the manufacture or production of any defense articles enumerated elsewhere in this category that are designated as Significant Military Equipment (SME) shall itself be designated SME.

Category XIII—Auxiliary Military Equipment

* * * * *

(b) * * *

(1) * * *

(x) Tracking, telemetry and control (TT&C) encryption/decryption when embedded in a commercial communications satellite identified in ECCN 9A004a of the Export Administration Regulations; embedded means that the device or system cannot feasibly be removed from the satellite

and that it cannot be used for other purposes.

* * * * *

Category XV—Spacecraft Systems and Associated Equipment

* (a) Spacecraft, including satellites, specifically designed or modified for military use.

(b) * * *

* (c) Military communications satellites or multi-mission satellites (including commercial communications satellites having additional, non-communication mission(s) or payload(s) controlled under this subchapter but not including ground stations and their associated equipment and technical data not enumerated elsewhere in § 121.1 of this subchapter; for controls on such ground stations see the Commerce Control List).

(d) * * *

(e) Systems, components, parts, accessories, attachments, and associated equipment (including ground support equipment) specifically designed, modified or configured for the articles in paragraphs (a) through (d) of this category, except as provided in paragraph (c).

(f) The following individual systems, components or parts (except when included in a commercial communications satellite licensed under ECCN 9A004a of the Export Administration Regulations):

(1) Anti-jam systems with the ability to respond to incoming interference by adaptively reducing antenna gain (nulling) in the direction of the interference.

(2) Antennas:

(i) With aperture (overall dimension of the radiating portions of the antenna) greater than 30 feet; or

(ii) With all sidelobes less than or equal to -35dB, relative to the peak of the main beam; or

(iii) Designed, modified, or configured to provide coverage area on the surface of the earth less than 200 nautical miles in diameter, where "coverage area" is defined as that area on the surface of the earth that is illuminated by the main beam width of the antenna (which is the angular distance between half power points of the beam).

(3) Intersatellite data relay links that do not involve a ground relay terminal ("cross-links").

(4) Spaceborne regenerative baseband processing equipment.

(5) Radiation-hardened microelectronic circuits that are specifically designed or rated to meet or exceed all five of the following characteristics:

(i) A total dose of 5×10⁵ Rads (SI);

- (ii) A dose rate upset of 5×10^8 Rads (SI)/Sec;
- (iii) A neutron dose of 1×10^{14} N/cm²;
- (iv) A single event upset of 1×10^{-7} or less error/bit/day;

(v) Single event latch-up free and having a dose rate latch-up of 5×10^8 Rads(SI)/sec or greater.

(6) Propulsion systems which permit acceleration of the satellite on-orbit (i.e., after mission orbit injection) at rates greater than 0.1g.

(7) Attitude control and determination systems designed to provide spacecraft pointing determination and control or payload pointing system control better than 0.02 degrees per axis.

(8) Orbit transfer engines ("kick-motors") which are embedded in the spacecraft. Orbit transfer engines which are not embedded in the spacecraft are controlled under Category IV of this subchapter (except as noted in the note for this paragraph (f)). Here "embedded" means that the device or system cannot feasibly be removed from the spacecraft and cannot be used for other purposes.

(9) Cryptographic items described in Category XIII(b)(1)(x) of this subchapter.

Note: Commercial communications satellites are subject to Commerce Licensing jurisdiction even if they include the individual munitions list systems, components or parts identified in paragraph (f) of this category. In all other cases, these systems, components or parts remain on the USML except non-embedded, solid propellant orbit transfer engines ("kick motors") are subject to Commerce licensing jurisdiction (and not controlled under this subchapter) when they are to be utilized for a specific commercial communications satellite launch, provided the solid propellant "kick motor" being utilized is not specifically designed or modified for military use or capable of being restarted after achievement of mission orbit (such orbit transfer engines are always controlled under Category IV of this subchapter). Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) related to the systems, components, or parts referred to in paragraph (f) of this category are always controlled under this subchapter, even when the satellite itself is licensed by the Department of Commerce.

(g) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to paragraphs (a) through (f) of this category. (See § 125.4 for exemptions.) Technical data directly related to the manufacture or production of any defense articles enumerated elsewhere in this category that are designated as Significant Military Equipment (SME) shall itself be designated SME. In addition, detailed design, development, production or manufacturing data for all

spacecraft systems and for specifically designed or modified components for all spacecraft systems, regardless of which U.S. Government agency has jurisdiction for export of the spacecraft. (See § 125.4 for exemptions.) This coverage by the U.S. Munitions List of detailed design, development, manufacturing or production information directly related to satellites which are not otherwise under the control of this section does not include that level of technical data (including marketing data) necessary and reasonable for a purchaser to have assurance that a U.S.-built item intended to operate in space has been designed, manufactured and tested in conformance with specified contract requirements (e.g., operational performance, reliability, lifetime, product quality, or delivery expectations), as well as data necessary to evaluate in-orbit anomalies and to operate and maintain associated ground equipment.

Note 1: All defense services and technical assistance for satellites and/or launch vehicles, including compatibility, integration, or processing data, is controlled under this subchapter. Technical data provided to the launch provider (form, fit, function, mass, electrical, mechanical, dynamic/environmental, telemetry, safety, facility, launch pad access, and launch parameters) for commercial communications satellites that describe the interfaces for mating and parameters for launch (e.g., orbit, timing) of the satellite is under Commerce jurisdiction.

Note 2: The international space station, being developed, launched and operated under the supervision of the National Aeronautics and Space Administration, is controlled for export purposes under the Export Administration Regulations.

Dated: October 25, 1996.

Lynn E. Davis,

Under Secretary for Arms Control and International Security Affairs.

[FR Doc. 96-28401 Filed 11-4-96; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Parts 92 and 176

Base Closure and Realignment; Redesignation of Parts

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule amends the heading of subchapter G to identify base closure and realignment documents and the redesignates part 92 as part 176.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: L.M. Bynum, 703-697-4111.

List of Subjects in 32 CFR Parts 92 and 176

Community development, Environmental protection, Government employees, Homeless military personnel, Surplus government property.

Accordingly, by the authority of 10 U.S.C. 301, 32 CFR Chapter I is amended as follows:

PART 92—[REDESIGNATED AS PART 176]

1. Part 92 is redesignated as part 176 and added to subchapter G.

1a. The authority citation for newly designated Part 176 continues to read as follows: 10 U.S.C. 2687 note.

§ 176.15 [Amended]

2. Newly redesignated 176.15, paragraph (b) is amended by revising "§§ 99.20 through 92.45" to read "§§ 176.20 through 176.45".

§ 176.20 [Amended]

3. Newly redesignated 176.20 is amended in paragraph (a) by revising "part 91" to read "part 175", paragraph (c) introductory text by revising "§ 92.20(a)" to read "§ 176.20(a)" both times it appears, paragraph (c)(1)(i) by revising "§ 92.10(b)" to read "§ 176.10(b)", paragraph (c)(3)(i) by revising "§ 92.20(c)(3)(ii)" to read "§ 176.20(c)(3)(ii)", paragraph (c)(3)(ii)(C) by revising "§ 92.20(c)(2)" to read "§ 176.20(c)(2)", paragraph (c)(5) by revising "§ 92.20(c)(1)" to read "§ 176.20(c)(1)" and by revising "§ 92.30" to read "§ 176.30".

§ 176.30 [Amended]

4. Newly redesignated 176.30 is amended in paragraph (b)(3)(i) by revising "§ 92.45(a)" to read "176.45(a)", paragraph (b)(5) by revising "§ 92.20(c)(3)" to read "§ 176.20(c)(3)", and paragraph (c) by revising "§ 99.20(c)(6)" to read "§ 176.20(c)(6)".

§ 176.35 [Amended]

5. Newly redesignated 176.35 is amended in paragraph (b)(4)(i) by revising "§ 92.20(c)(3)" to read "§ 176.20(c)(3)", paragraph (c)(1) introductory text by revising "§ 92.15(a)" to read "§ 176.15(a)", paragraph (c)(2) by revising "§ 92.20(c)(5)" to read "§ 176.20(c)(5)" and by revising "§ 92.40" to read "§ 176.40".