

Rectal Epithelium,” *Contraception*, 62:149–154, 2002.

20. Phillips, D. M. et al., “Lubricants Containing N–9 May Enhance Rectal Transmission of HIV and Other STIs,” *Contraception*, 70:107–110, 2004.

#### List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

#### PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.66 is amended by adding paragraph (c)(5)(ii)(H) to read as follows:

#### § 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

\* \* \* \* \*

(c) \* \* \*

(5) \* \* \*

(ii) \* \* \*

(H) Sexually transmitted diseases (STDs) warning for vaginal contraceptive and spermicide drug products containing nonoxynol 9 set forth in § 201.325(b)(2). This warning shall follow the subheading “Sexually transmitted diseases (STDs) alert:”

\* \* \* \* \*

■ 3. Section 201.325 is added to subpart G to read as follows:

#### § 201.325 Over-the-counter drugs for vaginal contraceptive and spermicide use containing nonoxynol 9 as the active ingredient; required warnings and labeling information.

(a) Studies indicate that use of vaginal contraceptive drug products containing nonoxynol 9 does not protect against infection from the human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), or against the transmission of other sexually transmitted diseases (STDs). Studies also indicate that use of vaginal contraceptive drug products containing nonoxynol 9 can increase vaginal irritation, such as the disruption of the vaginal epithelium, and also can cause epithelial disruption when used in the rectum. These effects may increase the risk of transmission of the AIDS virus (HIV) from an infected partner. Therefore, consumers should be warned

that these products do not protect against the transmission of the AIDS virus (HIV) or other STDs, that use of these products can increase vaginal and rectal irritation, which may increase the risk of getting the AIDS virus (HIV) from an HIV infected partner, and that the products are not for rectal use. Consumers should also be warned that these products should not be used by persons who have HIV/AIDS or are at high risk for HIV/AIDS.

(b) The labeling of OTC vaginal contraceptive and spermicide drug products containing nonoxynol 9 as the active ingredient, whether subject to the ongoing OTC drug review or an approved drug application, must contain the following warnings under the heading “Warnings,” in accordance with 21 CFR 201.66.

(1) “[bullet] For vaginal use only [bullet] Not for rectal (anal) use” [both warnings in bold type].

(2) “Sexually transmitted diseases (STDs) alert [in bold type]: This product does not [word “not” in bold type] protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner”.

(3) “Do not use” [in bold type] if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control”.

(4) “When using this product [in bold type] [optional, bullet] you may get vaginal irritation (burning, itching, or a rash)”.

(5) “Stop use and ask a doctor if [in bold type] [optional, bullet] you or your partner get burning, itching, a rash, or other irritation of the vagina or penis”.

(c) The labeling of this product states under the “Other information” section of the Drug Facts labeling in accordance with § 201.66(c)(7), “[bullet] when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of catching or spreading HIV, the virus that causes AIDS.

(d) The labeling of this product includes the following statements either on the outside container or wrapper of the retail package, under the “Other information” section of the Drug Facts labeling in accordance with § 201.66(c)(7), or in a package insert:

(1) “[bullet] studies have raised safety concerns that products containing the spermicide nonoxynol 9 can irritate the vagina and rectum. Sometimes this irritation has no symptoms. This irritation may increase the risk of getting HIV/AIDS from an infected partner”.

(2) “[bullet] you can use nonoxynol 9 for birth control with or without a diaphragm or condom if you have sex

with only one partner who is not infected with HIV and who has no other sexual partners or HIV risk factors”.

(3) “[bullet] use a latex condom without nonoxynol 9 if you or your sex partner has HIV/AIDS, multiple sex partners, or other HIV risk factors”.

(4) “[bullet] ask a health professional if you have questions about your best birth control and STD prevention methods”.

(e) Any drug product subject to this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after June 19, 2008, is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), is a new drug under section 505 of the act (21 U.S.C. 355), and is subject to regulatory action.

Dated: December 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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#### DEPARTMENT OF STATE

#### 22 CFR Part 124

[Public Notice 6031]

#### Amendment to the International Traffic in Arms Regulations: Regarding Dual and Third Country Nationals

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the text of the International Traffic in Arms Regulations (ITAR) to allow access to defense articles and services for dual and third country nationals of certain countries through revisions in procedures for technical assistance agreements and manufacturing licensing agreements. This regulatory change will reduce the burden on exporters of defense articles and on foreign parties to the agreements by reducing the number of individual Non Disclosure Agreements (NDA's) which must be executed and maintained on file.

**DATES:** *Effective Date:* This rule is effective December 19, 2007.

**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, ITAR

§§ 124.12 and 124.16, SA-1, 12th Floor, Washington, DC 20522-0112.

• *Hand delivery or Courier (regular work hours only)*: Department of State Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTENTION: Regulatory Change, ITAR §§ 124.12 and 124.16, SA-1, 12th Floor, 2401 E Street, NW., Washington, DC 20037.

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

**FOR FURTHER INFORMATION CONTACT:**

Acting Director Terry Davis, Office of Defense Trade Controls Licensing, Department of State, Telephone (202) 663-2739 or Fax (202) 663-3866, E-mail [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Regulatory Change, ITAR §§ 124.12 and 124.16.

**SUPPLEMENTARY INFORMATION:** The Department of State, Directorate of Defense Trade Controls (DDTC) has recently completed a review of licensing requirements for technical assistance and manufacturing license agreements (TAAs/MLAs) under Part 124 of the ITAR. The Department has long followed a procedure to license to all countries of ultimate destination, including to nationals of countries other than the country to which the items are to be exported under the TAA/MLA. In particular, § 124.8(5) precludes any retransfer of defense articles (hardware or technical data) or defense services pursuant to an approved TAA/MLA to third countries or nationals of third countries unless specifically authorized in the agreement or for which prior written approval has been granted by the Department. For export control purposes, DDTC has considered a third country national to be an individual from a country other than the country which is the foreign signatory to the agreement. A third country national may also be a dual national if he holds nationality from more than one country. In addition to citizenship, DDTC considers country of birth a factor in determining nationality.

Current procedures require that third country/dual nationals authorized under TAA/MLA's execute Non Disclosure Agreements (NDAs) before they receive access to defense articles or defense services. The changes to Part 124 would revise these procedures to permit the U.S. applicant to request further release of technical data and defense services and access to defense articles exported pursuant to or produced as a result of the TAA/MLA to third country/dual national employees of the foreign signatory who

are nationals exclusively from countries that are members of the North Atlantic Treaty Organization (NATO), the European Union (EU), Australia, Japan, New Zealand, and Switzerland. These procedural changes would also apply to employees of sub-licensees authorized under the agreement. Execution of NDAs by individuals who are third country or dual nationals meeting the preceding criteria would not be required. These changes are being implemented by an additional clause in the transmittal letter required under § 124.12 (c) whereby the applicant will request retransfer of defense articles and services to third country/dual nationals from these countries under the authority of a new ITAR § 124.16 entitled "Special Retransfer Authorizations for Unclassified Technical Data and Defense Services to Member States of NATO and the European Union, Australia, Japan, New Zealand, and Switzerland."

**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 required by 5 U.S.C. 553 and 554.

*Regulatory Flexibility Act*

This rule does not require analysis under the Regulatory Flexibility Act.

*Unfunded Mandates Act of 1995*

This rule does not require analysis under the Unfunded Mandates Reform Act.

*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*

It is determined that this rule does not have sufficient federalism implications to warrant application of the consultation provisions of Executive Orders 12372 and 13132.

*Executive Order 12866*

This amendment is exempt from the 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 124**

Arms and Munitions, Exports, Technical Assistance.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 124 is amended as follows:

**PART 124—AGREEMENTS, OFFSHORE PROCUREMENT AND OTHER DEFENSE SERVICES**

■ 1. The authority citation for part 124 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. 2651a; 22 U.S.C. 2776; Pub L. 105-261.

■ 2. Section 124.12 is amended by adding a new paragraph (a)(10) to read as follows:

**§ 124.12 Required information in letters of transmittal.**

(a) \* \* \*

(10) A statement specifying whether the applicant is requesting retransfer of defense articles and defense services pursuant to § 124.16 of this subchapter.

\* \* \* \* \*

■ 3. Section 124.16 is added to read as follows:

**§ 124.16 Special Retransfer Authorizations for Unclassified Technical Data and Defense Services to Member States of NATO and the European Union, Australia, Japan, New Zealand, and Switzerland.**

The provisions of § 124.8(5) of this subchapter notwithstanding, pursuant to this subsection the Department may approve access to unclassified defense articles exported in furtherance of or produced as a result of a TAA/MLA, and retransfer of technical data and defense services to individuals who are third country/dual national employees of the foreign signatory or its approved sub-licensees provided they are nationals exclusively of countries that are members of NATO the European Union, Australia, Japan, New Zealand, and Switzerland and their employer is a signatory to the agreement or has executed a Non Disclosure Agreement. The retransfer must take place completely within the physical territories of these countries or the United States. Permanent retransfer of hardware is not authorized.

Dated: November 27, 2007.

**John C. Rood,**

*Acting Under Secretary for Arms Control and International Security, Department of State.*

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