

Use	Limitations
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9. For control of <i>Salmonella</i> in fresh shell eggs.	Not to exceed 3.0 kGy.

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Dated: July 14, 2000.
L. Robert Lake,
Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.
 [FR Doc. 00-18496 Filed 7-20-00; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for topical veterinary prescription use of selamectin solution for the additional indication for control of intestinal hookworm and roundworm infections in cats.

DATES: This rule is effective July 21, 2000.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-152 that provides for topical veterinary prescription use of Revolution™ (selamectin) in dogs and cats for the additional indication for control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. The supplemental NADA is approved as of June 13, 2000, and the regulations are amended in 21 CFR 524.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of

safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.2098 is amended by revising the third sentence in paragraph (d)(2) to read as follows:

§ 524.2098 Selamectin.

* * * * *

(d) * * *

(2) * * * Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. * * *

Dated: July 3, 2000.
David R. Newkirk,
Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
 [FR Doc. 00-18458 Filed 7-20-00; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Parts 124, 125 126

[Public Notice 3365]

Amendments to the International Traffic in Arms Regulation: NATO Countries, Australia and Japan

AGENCY: Bureau of Political-Military Affairs, Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic In Arms Regulations to implement reforms announced by the Secretary of State at the NATO Ministerial in Florence, Italy on May 24, 2000. The reforms of the U.S. export controls system are available to NATO Allies, Japan and Australia and are intended to streamline the U.S. defense export control licensing process and forge closer industrial linkage between the U.S. and allied defense suppliers. It is contemplated that it will increase our mutual security by enhancing NATO member defense capabilities, promoting interoperability with our allies and friends and promoting trans-Atlantic defense industrial cooperation. Part 124 of the International Traffic In Arms Regulations is being amended to permit U.S. companies to perform, using an exemption, certain maintenance and maintenance training for NATO government, Australia and Japan on US-origin inventoried defense articles. Part 125 is amended to provide authorization, without a license, to transfer technical data to support procurement of defense articles from defense firms in NATO countries,

Australia and Japan for use in the United States. This amendment also establishes four comprehensive export authorizations for use in circumstances where the full parameters of a commercial export endeavor, including the needed defense exports, can be well anticipated and described in advance.

EFFECTIVE DATE: September 1, 2000.

FOR FURTHER INFORMATION CONTACT: Rose Biancaniello, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State ATTN: Regulatory Change NATO, Australia and Japan at (202) 663-2862 or FAX (202) 261-8264.

SUPPLEMENTARY INFORMATION: In implementing the Secretary of State's announcement at the NATO Ministerial, May 24, 2000, in Florence, Italy, the International Traffic In Arms Regulations is being amended. Section 124.2 is amended to add a new paragraph (c) to permit U.S. companies to provide, without a license, defense services necessary to perform maintenance on and maintenance training for inventoried US-origin equipment of NATO countries, Australia and Japan, provided the maintenance and maintenance training does not result in any modification, enhancement, upgrade or other form of alteration or improvement that enhances the performance or capability of the defense article. Also, the export must not include the transfer of certain technologies; such as, design methodology, engineering analysis and manufacturing know-how. Section 125.4 is amended to add a new paragraph (c) to permit the transfer of technical data to NATO countries, Australia and Japan of technical data necessary to support offshore procurement of defense articles for use in the United States. In addition, Part 126 is amended to add, in § 126.9, a new paragraph (b) and a new § 126.14. These additions are being made to create four new comprehensive authorizations developed to limit the number of export approvals necessary to authorize the export of U.S. technology to NATO countries, Australia and Japan that will encourage government-to-government cooperative research and development, support joint ventures and teaming arrangements and facilitate a U.S. company's role in a cooperative project when covered by a government-to-government Memorandum of Understanding (MOU).

In implementing these initiatives, Part 124, 125, and 126 are being amended.

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. It 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. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the States, 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 § 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Order Nos. 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, NATO, Australia and Japan, 13th Floor, H1304, 2401 E Street, NW., Washington, DC 20037. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (DTC) pursuant to the registration requirements of § 38 of the Arms Export Control Act.

List of Subjects

22 CFR Part 124

Arms and munitions, Exports, Technical assistance.

22 CFR Part 125

Arms and munitions, Exports.

22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 124, 125 and 126, are being 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. 2658; Pub L. 105-261.

2. Section 124.2 is amended by adding paragraph (c) to read as follows:

§ 124.2 Exemptions for training and military service.

* * * * *

(c) NATO countries, Australia and Japan, in addition to the basic maintenance training exemption

provided in § 124.2(a) and basic maintenance information exemption in § 125.4(b)(5), no technical assistance agreement is required for maintenance training or the performance of maintenance, including the export of supporting technical data, when the following criteria can be met:

(1) Defense services are for unclassified U.S.-origin defense articles lawfully exported or authorized for export and owned or operated by and in the inventory of NATO or the Federal Governments of NATO countries, Australia or Japan;

(2) This defense service exemption does not apply to any transaction involving defense services for which congressional notification is required in accordance with § 123.15 and § 124.11 of this subchapter.

(3) Maintenance training or the performance of maintenance must be limited to inspection, testing, calibration or repair, including overhaul, reconditioning and one-to-one replacement of any defective items, parts or components; and excluding any modification, enhancement, upgrade or other form of alteration or improvement that enhances the performance or capability of the defense article. This does not preclude maintenance training or the performance of maintenance that would result in enhancements or improvements only in the reliability or maintainability of the defense article, such as an increased mean time between failure (MTBF).

(4) Supporting technical data must be unclassified and must not include software documentation on the design or details of the computer software, software source code, design methodology, engineering analysis or manufacturing know-how such as that described in paragraphs (c)(4)(i) through (c)(4)(iii) as follows:

(i) *Design Methodology*, such as: The underlying engineering methods and design philosophy utilized (*i.e.*, the "why" or information that explains the rationale for particular design decision, engineering feature, or performance requirement); engineering experience (*e.g.* lessons learned); and the rationale and associated databases (*e.g.* design allowables, factors of safety, component life predictions, failure analysis criteria) that establish the operational requirements (*e.g.*, performance, mechanical, electrical, electronic, reliability and maintainability) of a defense article.

(ii) *Engineering Analysis*, such as: Analytical methods and tools used to design or evaluate a defense article's performance against the operational requirements. Analytical methods and

tools include the development and/or use of mockups, computer models and simulations, and test facilities.

(iii) *Manufacturing Know-how*, such as: Information that provides detailed manufacturing processes and techniques needed to translate a detailed design into a qualified, finished defense article.

(5) This defense service exemption does not apply to maintenance training or the performance of maintenance and service or the transfer of supporting technical data for the following defense articles:

(i) All Missile Technology Control Regime Annex Items;

(ii) Firearms listed in Category I; and ammunition listed in Category III for the firearms in Category I;

(iii) Nuclear weapons strategic delivery systems and all components, parts, accessories and attachments specifically designed for such systems and associated equipment;

(iv) Naval nuclear propulsion equipment listed in Category VI(e);

(v) Gas turbine engine hot sections covered by Categories VI(f) and VIII(b);

(vi) Category VIII(f);

(vii) Category XIII(c);

(viii) Chemical agents listed in Category XIV (a), biological agents in Category XIV (b), and equipment listed in Category XIV (c) for dissemination of the chemical agents and biological agents listed in Categories XIV (a) and (b);

(ix) Nuclear radiation measuring devices manufactured to military specifications listed in Category XIV(d);

(x) Category XV;

(xi) Nuclear weapons design and test equipment listed in Category XVI;

(xii) Submersible and oceanographic vessels and related articles listed in Category XX(a) through (d);

(xiii) Miscellaneous articles covered by Category XXI.

(6) *Eligibility Criteria for Foreign Persons*. Foreign persons eligible to receive technical data or maintenance training under this exemption are limited to nationals of the NATO countries, Australia or Japan.

PART 125—LICENSES FOR THE EXPORT OF TECHNICAL DATA AND CLASSIFIED DEFENSE ARTICLES

3. The authority citation for part 125 continues to read as follows:

Authority: Sections 2 and 38, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778); E.O. 11958, 42 FR 4311, 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658.

4. Section 125.4 is amended by revising paragraph (a) and by adding paragraph (c) to read as follows:

§ 125.4 Exemptions of general applicability.

(a) The following exemptions apply to exports of technical data for which approval is not needed from the Office of Defense Trade Controls. These exemptions, except for paragraph (b)(13) of this section, do not apply to exports to proscribed destinations under § 126.1 of this subchapter or for persons considered generally ineligible under § 120.1(c) of this subchapter. The exemptions are also not applicable for purposes of establishing offshore procurement arrangements or producing defense articles offshore (see § 124.13), except as authorized under § 125.4 (c). If § 126.8 of this subchapter requirements are applicable, they must be met before an exemption under this section may be used. Transmission of classified information must comply with the requirements of the National Industrial Security Program Operating Manual and the exporter must certify to the transmittal authority that the technical data does not exceed the technical limitation of the authorized export.

(b) * * *

(c) Defense services and related unclassified technical data are exempt from the licensing requirements of this subchapter, to nationals of NATO countries, Australia and Japan, for the purposes of responding to a written request from the Department of Defense for a quote or bid proposal. Such exports must be pursuant to an official written request or directive from an authorized official of the U.S. Department of Defense. The defense services and technical data are limited to those listed in paragraphs (c)(1), (c)(2), and (c)(3) and must not include those listed in paragraphs (c)(4), (c)(5), and (c)(6) which follow:

(1) *Build-to-Print*. “Build-to-Print” means that a foreign consignee can produce a defense article from engineering drawings without any technical assistance from a U.S. exporter. This transaction is based strictly on a “hands-off” approach since the foreign consignee is understood to have the inherent capability to produce the defense article and only lacks the necessary drawings. Supporting documentation such as acceptance criteria, and specifications, may be released on an as-required basis (*i.e.* “must have”) such that the foreign consignee would not be able to produce an acceptable defense article without this additional supporting documentation. Documentation which is not absolutely necessary to permit manufacture of an acceptable defense article (*i.e.* “nice to have”) is not

considered within the boundaries of a “Build-to-Print” data package;

(2) *Build/Design-to-Specification*. “Build/Design-to-Specification” means that a foreign consignee can design and produce a defense article from requirement specifications without any technical assistance from the U.S. exporter. This transaction is based strictly on a “hands-off” approach since the foreign consignee is understood to have the inherent capability to both design and produce the defense article and only lacks the necessary requirement information;

(3) *Basic Research*. “Basic Research” means a systemic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and observable facts without specific applications towards processes or products in mind. It does not include “Applied Research” (*i.e.* a systemic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met. It is a systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.);

(4) *Design Methodology*, such as: The underlying engineering methods and design philosophy utilized (*i.e.*, the “why” or information that explains the rationale for particular design decision, engineering feature, or performance requirement); engineering experience (*e.g.* lessons learned); and the rationale and associated databases (*e.g.* design allowables, factors of safety, component life predictions, failure analysis criteria) that establish the operational requirements (*e.g.*, performance, mechanical, electrical, electronic, reliability and maintainability) of a defense article. (Final analytical results and the initial conditions and parameters may be provided.)

(5) *Engineering Analysis*, such as: Analytical methods and tools used to design or evaluate a defense article’s performance against the operational requirements. Analytical methods and tools include the development and/or use of mockups, computer models and simulations, and test facilities. (Final analytical results and the initial conditions and parameters may be provided.)

(6) *Manufacturing Know-how*, such as: information that provides detailed manufacturing processes and techniques needed to translate a detailed design into a qualified, finished defense article. (Information may be provided in a

build-to-print package that is necessary in order to produce an acceptable defense article.)

PART 126—GENERAL POLICIES AND PROVISIONS

5. The authority citation for Part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2778; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p.79; 22 U.S.C. 2658; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR 1994 Comp., p 899.

6. Section 126.9 is revised to read as follows:

§ 126.9 Advisory opinions and related authorizations.

(a) Any person desiring information as to whether the Office of Defense Trade controls would be likely to grant a license or other approval for the export or approval of a particular defense article or defense service to a particular country may request an advisory opinion from the Office of Defense Trade Controls. These opinions are not binding on the Department of State and are revocable. A request for an advisory opinion must be made in writing and must outline in detail the equipment, its usage, the security classification (if any) of the articles or related technical data, and the country or countries involved. An original and seven copies of the letter must be provided along with seven copies of suitable descriptive information concerning the defense article or defense service.

(b) *Related authorizations.* The Office of Defense Trade Controls may, as appropriate, in accordance with the procedures set forth in paragraph (a) of this section, provide export authorization, subject to all other relevant requirements of this subchapter, both for transactions that have been the subject of advisory opinions requested by prospective U.S. exporters, or for the Office's own initiatives. Such initiatives may cover pilot programs, or specifically anticipated circumstances for which the Office considers special authorizations appropriate.

7. Section 126.14 is added to read as follows:

§ 126.14. Special comprehensive export authorizations for NATO, Australia, and Japan.

(a) With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide the comprehensive authorizations described below for circumstances where the full parameters of a commercial export

endeavor including the needed defense exports can be well anticipated and described in advance, thereby making use of such comprehensive authorizations appropriate.

(1) *Major Project Authorization.* With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide comprehensive authorizations for well circumscribed commercially developed “major projects”, where a principal registered U.S. exporter/prime contractor identifies in advance the broad parameters of a commercial project including defense exports needed, other participants (e.g., exporters with whom they have “teamed up”, subcontractors), and foreign government end users. Projects eligible for such authorization may include a commercial export of a major weapons system for a foreign government involving, for example, multiple U.S. suppliers under a commercial teaming agreement to design, develop and manufacture defense articles to meet a foreign government's requirements. U.S. exporters seeking such authorization must provide detailed information concerning the scope of the project, including other exporters, U.S. subcontractors, and planned exports (including re-exports) of defense articles, defense services, and technical data, and meet the other requirements set forth in paragraph (b) of this section.

(2) *Major Program Authorization.* With respect to NATO members, Australia, and Japan, the Office of Defense Trade Controls may provide comprehensive authorizations for well circumscribed commercially developed “major program”. This variant would be available where a single registered U.S. exporter defines in advance the parameters of a broad commercial program for which the registrant will be providing all phases of the necessary support (including the needed hardware, tech data, defense services, development, manufacturing, and logistic support). U.S. exporters seeking such authorization must provide detailed information concerning the scope of the program, including planned exports (including re-exports) of defense articles, defense services, and technical data, and meet the other requirements set forth below in paragraph (b) of this section.

(3)(i) *Global Project Authorization.* With respect to NATO members, Australia and Japan, the Office of Defense Trade Controls may provide a comprehensive “Global Project Authorization” to registered U.S. exporters for exports of defense articles, technical data or defense services in

support of government to government cooperative projects (covering research and development or production) with one of these countries undertaken pursuant to an agreement between the USG and the government of such country, or a memorandum of understanding between the Department of Defense and the country's Ministry of Defense.

(ii) A set of standard terms and conditions derived from and corresponding to the breadth of the activities and phases covered in such a cooperative MOU will provide the basis for this comprehensive authorization for all U.S. exporters (and foreign end users) identified by DoD as participating in such cooperative project. Such authorizations may cover a broad range of defined activities in support of such programs including multiple shipments of defense articles and technical data and performance of defense services for extended periods, and re-exports to approved end users.

(iii) Eligible end users will be limited to ministries of defense of MOU signatory countries and foreign companies serving as contractors of such countries.

(iv) Any requirement for non-transfer and use assurances from a foreign government may be deemed satisfied by the signature by such government of a cooperative agreement or by its ministry of defense of a cooperative MOU where the agreement or MOU contains assurances that are comparable to that required by a DSP–83 with respect to foreign governments and that clarifies that the government is undertaking responsibility for all its participating companies. The authorized non-government participants or end users (e.g., the participating government's contractors) will still be required to execute DSP–83's.

(4) *Technical Data Supporting an Acquisition, Teaming Arrangement, Merger, Joint Venture Authorization.* With respect to NATO member countries, Australia and Japan, the Office of Defense Trade Controls may provide a registered U.S. defense company a comprehensive authorization to export technical data in support of the U.S. exporter's consideration of entering into a teaming arrangement, joint venture, merger, acquisition, or similar arrangement with prospective foreign partners. Specifically the authorization is designed to permit the export of a broadly defined set of technical data to qualifying well established foreign defense firms in NATO countries, Australia or Japan in order to better facilitate a sufficiently in depth

assessment of the benefits, opportunities and other relevant considerations presented by such prospective arrangements. U.S exporters seeking such authorization must provide detailed information concerning the arrangement, joint venture, merger or acquisition, including any planned exports of defense articles, defense services, and technical data, and meet the other requirements set forth in paragraph (b) of this section.

(b) *Provisions and Requirements for Comprehensive Authorizations.* Requests for the special comprehensive authorizations set forth in paragraph (a) of this section should be by letter addressed to the Office of Defense Trade Control. With regard to a commercial major program or project authorization, or technical data supporting a teaming arrangement, merger, joint venture or acquisition, registered U.S. exporters may consult the Director of the Office of Defense Trade Controls about eligibility for and obtaining available comprehensive authorizations set forth in paragraph (a) of this section or pursuant to § 126.9(b).

(1) Requests for consideration of all such authorizations should be formulated to correspond to one of the authorizations set out in paragraph (a) of this section, and should include:

- (i) A description of the proposed program or project, including where appropriate a comprehensive description of all phases or stages; and
- (ii) Its value; and
- (iii) Types of exports needed in support of the program or project; and
- (iv) Projected duration of same, within permissible limits; and
- (v) Description of the exporter's plan for record keeping and auditing of all phases of the program or project; and
- (vi) In the case of authorizations for exports in support of government to government cooperative projects, identification of the cooperative project.

(2) Amendments to the requested authorization may be requested in writing as appropriate, and should include a detailed description of the aspects of the activities being proposed for amendment.

(3) The comprehensive authorizations set forth in paragraph (a) of this section may be made valid for the duration of the major commercial program or project, or cooperative project, not to exceed 10 years.

(4) Included among the criteria required for such authorizations are those set out in Part 124, *e.g.*, §§ 124.7, 124.8 and 124.9, as well as §§ 125.4 (technical data exported in furtherance of an agreement) and 123.16 (hardware being included in an agreement).

Provisions required will also take into account the congressional notification requirements in §§ 123.15 and 124.11 of the ITAR. Specifically, comprehensive congressional notifications corresponding to the comprehensive parameters for the major program or project or cooperative project should be possible, with additional notifications such as those required by law for changes in value or other significant modifications.

(5) All authorizations will be consistent with all other applicable requirements of the ITAR, including requirements for non-transfer and use assurances (see §§ 123.10 and 124.10), congressional notifications (*e.g.*, §§ 123.15 and 124.11), and other documentation (*e.g.*, §§ 123.9 and 126.13).

(6) Special auditing and reporting requirements will also be required for these authorizations. Exporters using special authorizations are required to establish an electronic system for keeping records of all defense articles, defense services and technical data exported and comply with all applicable requirements for submitting shipping or export information within the allotted time.

Dated: July 14, 2000.

Pamela L. Frazier,

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

[FR Doc. 00-18530 Filed 7-20-00; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Part 126

[Public Notice 3366]

Amendment to the International Traffic in Arms Regulation: FMS LOA Authorized Defense Services

AGENCY: Bureau of Political-Military Affairs, Department of State.

ACTION: Final rule.

SUMMARY: The International Traffic In Arms Regulations (ITAR), § 126.6, Foreign-owned military aircraft and naval vessels, and the Foreign Military Sales program is being amended to clarify the use of the exemption when providing defense services authorized by the Foreign Military Sales (FMS) Program.

EFFECTIVE DATE: September 1, 2000.

FOR FURTHER INFORMATION CONTACT: Rose Biancianiello, Deputy Director,

Licensing, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State ATTN: Regulatory Change, Section 126.6 FMS Defense Service at (202) 663-2862 or FAX (202) 261-8264.

SUPPLEMENTARY INFORMATION: Section 126.6 currently provides for the export of defense services when authorized by the Foreign Military Sales (FMS) Program without a license or other approval. However, companies, lacking clear guidance often sought approval of the Office of Defense Trade Controls which delayed the provision of the service or frequently also entailed seeking assurances that the foreign government believed it had already provided to the USG. Thus, this amendment to § 126.6 which clarifies the exemption on the basis of specific criteria will assist registered defense firms by making it clear when to use the exemption to provide defense services authorized by the Department of Defense in an LOA.

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. It 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. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the Nation, USG or any State, 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 section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Order Nos. 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, FMS LOA Authorized Defense Services, 13th Floor, Room H1304, 2401 E Street, N.W., Washington, D.C. 20037. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (ODTC) pursuant to the registration requirements of section 38 of the Arms Export Control Act.