

Incorporation by Reference Material

(c) The actions specified in this AD must be done in accordance with the following Rolls-Royce Olympus service bulletin:

Document No.	Pages	Revision	Date
OL-593-71-9056-33	1	2	Dec. 7, 2000.
	2-3	Original	Oct. 5, 1998.
	4	2	Dec. 7, 2000.
	5	1	Feb. 19, 1999.
	6	Original	Oct. 5, 1998.
	7	2	Dec. 7, 2000.
	8	1	Feb. 19, 1999.
	Total pages: 8		

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Rolls-Royce Defence (Europe) Technical Publications Department, P.O. Box 3, Filton, Bristol BS34 7QE, England; telephone 011 44 7979 6060; FAX 011 44 7979 7234. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in CAA airworthiness directive 002-10-98.

Effective Date of This AD

(d) This amendment becomes effective on August 9, 2001.

Issued in Burlington, Massachusetts, on June 28, 2001.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01-16926 Filed 7-9-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Powder

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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for oral use of chlortetracycline soluble powder in solutions administered to cattle, swine, chickens, and turkeys for the control and treatment of various bacterial diseases. Technical amendments are also being made.

DATES: This rule is effective July 10, 2001.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION:

Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed ANADA 200-295 for Pennchlor™ 64 (chlortetracycline) Soluble Powder. The application provides for oral use of chlortetracycline soluble powder administered in drinking water or in solutions dosed by mouth in cattle, swine, chickens, and turkeys for the control and treatment of various diseases caused by bacteria susceptible to chlortetracycline. Pennfield Oil Co.'s Pennchlor™ 64 is approved as a generic copy of American Cyanamid's Aureomycin® (chlortetracycline) Soluble Powder Concentrate, approved under NADA 65-440. The ANADA is approved as of April 27, 2001, and the regulations are amended in 21 CFR 520.445b to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 520.445b is further amended in paragraph (d)(4)(iii)(C) by removing the Pennfield Oil Co. drug labeler code (DLC #053389) which was added in error (59 FR 39438, August 3, 1994) and by correcting the drug labeler code for ADM Animal Health & Nutrition Division (DLC #017519) which in error was not changed in this paragraph when the drug labeler code was changed elsewhere in this section (62 FR 27691, May 21, 1997). Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

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.

The agency has determined under 21 CFR 25.33(a)(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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (b) by removing "as in paragraphs (d)(1)(i)(A) and (d)(2)(i)(A)" and adding in its place "as in paragraph (d)"; and in paragraph (d)(4)(iii)(C) by removing ", 012286, and 053389" and adding in its place "and 017519".

Dated: June 27, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-17104 Filed 7-9-01; 8:45 am]

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DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Parts 124, 125, and 126

[Public Notice 3710]

Amendment to the International Traffic in Arms Regulation: Sweden

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic In Arms Regulations to extend a recent reform of the U.S. defense trade export control system, originally intended to benefit NATO, Australia and Japan, to Sweden. The recent reforms were intended to streamline the U.S. defense export control licensing process and forge closer industrial linkage between the U.S. and allied defense suppliers. Part 124 of the International Traffic In Arms Regulations is now being amended to permit U.S. companies to perform, using an exemption, certain maintenance and maintenance training for US-origin defense articles in the inventory of Sweden. Part 125 is amended to provide authorization, without a license, to transfer certain technical data to support procurement of defense articles from defense firms in Sweden for use by the Department of Defense. In addition, under Part 126, the 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, is now available for Sweden.

EFFECTIVE DATE: July 10, 2001.

FOR FURTHER INFORMATION CONTACT: William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State, ATTN: Regulatory Change Sweden at (202) 663-2861 or FAX (202) 261-8264.

SUPPLEMENTARY INFORMATION: On July 21, 2000, the Department published regulations to implement, effective September 1, 2000, the U.S. Defense Trade Security Initiative (DTSI) announced at the NATO Ministerial in Florence, Italy on May 24, 2000 (65 FR 45282). Those reforms of the U.S. defense trade export control system were made available to NATO Allies,

Japan and Australia. Those initiatives were intended to improve the efficiency and competition in defense markets with NATO allies, Japan and Australia. This particular amendment to the International Traffic in Arms Regulations would make those reforms available with respect to Sweden. These reforms 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.

Section 124.2(c) is amended to add Sweden. Paragraph (c) permits U.S. companies to provide, without a license, defense services necessary to perform maintenance on and maintenance training for US-origin equipment in the inventory of NATO, NATO countries, Australia, Japan, and Sweden, 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(c) is amended to add Sweden. Paragraph (c) permits the transfer to NATO countries, Australia, Japan, and Sweden, of technical data necessary to support offshore procurement of defense articles for use by the Department of Defense. In addition, section 126.14 is amended to include Sweden in the four comprehensive export authorizations developed to limit the number of individual export approvals necessary to authorize the export of defense articles to NATO countries, Australia, Japan, and Sweden, which 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, parts 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 section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Orders 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, Sweden, 13th Floor, H1304, 2401 E Street, NW., Washington, DC20037. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (DTC) pursuant to the registration requirements of section 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, Classified information, Exports.

22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Parts 124, 125 and 126, are 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 revising paragraphs (c) introductory text, (c)(1), and (c)(6) to read as follows:

§ 124.2 Exemptions for training and military service.

* * * * *

(c) NATO countries, Australia, Japan, and Sweden, in addition to the basic maintenance training exemption provided in § 124.2(a) and basic maintenance information exemption in § 125.4(b)(5) of this subchapter, no technical assistance agreement is required for maintenance training or the performance of maintenance, including