

(B) * * *
(3) * * * Zero-day withdrawal for those products sponsored by No. 053389.

(C) * * *
(3) * * * Zero-day withdrawal for those products sponsored by No. 053389.

* * * * *

Dated: February 26, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-6807 Filed 3-19-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Tilmicosin

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA for veterinary prescription use of tilmicosin Type C medicated swine feeds under a veterinary feed directive (VFD) provides a revised limitation to prevent accidental access by horses. Also, FDA amends the regulation to provide a swine muscle tolerance and an acceptable daily intake (ADI).

EFFECTIVE DATE: March 22, 1999.

FOR FURTHER INFORMATION CONTACT:

William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7570.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of NADA 141-064 that provides for the use of Pulmotil® (tilmicosin) Type A medicated article to make Type B and Type C medicated swine feeds for control of swine respiratory disease. The drug is limited to use by or on the order of a licensed veterinarian under an approved VFD. The firm filed a supplemental NADA that provided for a revised limitation to prevent accidental access by horses. Also, FDA reviewed the information in the application and revised the regulation to provide an ADI

and a swine muscle tolerance. The supplemental NADA is approved as of February 2, 1999, and the regulations in 21 CFR 556.735 and 558.618 are amended to reflect the approval. The basis for 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 supplemental 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.

List of Subjects

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.735 is revised to read as follows:

§ 556.735 Tilmicosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tilmicosin is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances—*(1) *Cattle.* A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 1.2 parts per million (ppm).

(2) *Swine.* A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 7.5 ppm and in muscle at 0.1 ppm.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.618 is amended in paragraph (d)(3) by adding a new sentence after the second sentence to read as follows:

§ 558.618 Tilmicosin

* * * * *

(d) * * *

(3) * * * Do not allow horses or other equine access to feeds containing tilmicosin. * * *

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Dated: February 26, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF STATE

22 CFR Parts 121 and 124

[Public Notice 3011]

Amendments to the International Traffic in Arms Regulations (ITAR): Control of Commercial Communications Satellites on the United States Munitions List

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) by re-designating on the U.S. Munitions List (USML) commercial communications satellites. **EFFECTIVE DATE:** March 15, 1999.

FOR FURTHER INFORMATION CONTACT:

William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State, Telephone (703) 812-2564 or FAX (703) 875-6647 ATTN: Regulatory Change, Commercial Communications Satellites.

SUPPLEMENTARY INFORMATION: On October 17, 1998, the President signed Public Law 105-261, The Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. This Act requires that, inter alia, effective March 15, 1999, communications satellites and related items (as defined in the Act) be controlled on the U.S. Munitions List, except with respect to export licenses for such satellites issued by the Department of Commerce before March 15, 1999 and export license applications

made under the Export Administration Regulations before March 15, 1999.

This coverage by the U.S. Munitions List does not extend to NASA's International Space Station, which remains subject to the Commerce Control List as set forth in 59 Fed. Regis. 47799 (1994).

Importantly, however, this rule change does provide for U.S. Munitions List coverage for all other spacecraft, including all satellites, and all spacecraft technical data, as well as all components, accessories, attachments, and related technical assistance, including, without exception, all launch support activities (e.g., technical data provided to the launch provider on form, fit, function, mass, electrical, mechanical, dynamic, environmental, telemetry, safety, facility, launch pad access, and launch parameters, as well as interfaces for mating and parameters for launch). The Office of Defense Trade Controls will be contacting U.S. persons individually who have received commodity jurisdiction determinations in the past that are affected by this rule change.

Consistent with Public Law 105-261, special export controls are detailed for the launch of U.S.-origin satellites and components from or by nationals of countries other than NATO (i.e., Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Turkey, the United Kingdom and the United States) or major non-NATO allies (i.e. Australia, Egypt, Israel, Japan, Republic of Korea, New Zealand, Jordan, and Argentina). The mandatory munitions licensing requirement of Public Law 105-261 for launch failure investigations and analyses is also elaborated, though such requirement has long existed in the ITAR. The Office of Defense Trade Controls generally will require a technical assistance agreement for the launch of U.S.-origin satellites and components from or by nationals of countries other than NATO or major non-NATO allies. Similarly, the Office of Defense Trade Controls generally will not authorize use of exemptions (e.g., § 124.3 and § 125.4(b)(2)) for shipments of unclassified technical data in furtherance of a technical assistance agreement in these circumstances unless the applicant has established a computerized document control and archive system for all such technical data and made provision for remote on-line access to the system by the Departments of State and Defense.

In carrying out this directive, Part 121 of Categories XIII and XV of the U.S. Munitions List (Part 121), and Part 124

concerning agreements and other defense services are 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 also exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This amendment has been found to be a minor rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996, P.L. 104-121. It 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, Communications Satellites and Related Items, Room 200, SA-6, Washington, D.C. 2052-0602.

List of Subjects

22 CFR Part 121

Arms and Munitions, Exports.

22 CFR Part 124

Arms and Munitions, Exports, Technical assistance.

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 is revised 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. In section 121.1, Category XIII is amended by revising paragraph (b)(1) and by removing (b)(1)(i), and Category XV is amended by revising paragraphs (a) and (b); removing paragraph (c); redesignating paragraph (d) as paragraph (c); redesignating paragraph (b)(5) as (d) and paragraphs (f)(5) (i) through (v) as (d)(1) through (5); revising newly designated paragraph (d) introductory text; revising paragraph (e) and (f); and removing paragraph (g), to read as follows:

§ 121.1 General—The United States Munitions List.

* * * * *

Category XIII—Auxiliary Military Equipment

* * * * *

(b) * * *

(1) Military cryptographic (including key management) systems, equipment, assemblies, modules, integrated circuits, components or software with the capability of maintaining secrecy or confidentiality of information or information systems, including equipment and software for tracking, telemetry and control (TT&C) encryption and decryption.

Category XV—Space Systems and Associated Equipment

* (a) Spacecraft, including communications satellites, remote sensing satellites, scientific satellites, research satellites, navigation satellites, experimental and multi-mission satellites.

***Note to paragraph (a):** Commercial communications satellites, scientific satellites, research satellites and experimental satellites are designated as SME only when the equipment is intended for use by the armed forces of any foreign country.

(b) Ground control stations for telemetry, tracking and control of spacecraft or satellites, or employing any of the cryptographic items controlled under category XIII of this subchapter.

* * * * *

(d) Radiation-hardened microelectronic circuits that meet or exceed all five of the following characteristics:

* * * * *

(e) All specifically designed or modified systems, components, parts, accessories, attachments, and associated equipment for the articles in this category, including the articles identified in § 1516 of Public Law 105-261: satellite fuel, ground support equipment, test equipment, payload adapter or interface hardware, replacement parts, and non-embedded solid propellant orbit transfer engines (see also categories IV and V).

(f) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the articles enumerated in paragraphs (a) through (e) of this category, as well as detailed design, development, manufacturing or production data for all spacecraft and specifically designed or modified components for all spacecraft systems. This paragraph includes all technical data, without exception, for all launch support activities (e.g., technical data provided to the launch provider on form, fit, function, mass, electrical, mechanical, dynamic, environmental, telemetry, safety, facility, launch pad access, and launch parameters, as well as interfaces for mating and parameters

for launch.) (See § 124.1 for the requirements for technical assistance agreements before defense services may be furnished even when all the information relied upon by the U.S. person in performing the defense service is in the public domain or is otherwise exempt from the licensing requirements of this subchapter.) Technical data directly related to the manufacture or production of any article enumerated elsewhere in this category that is designated as Significant Military Equipment (SME) shall itself be designated SME. Further, technical data directly related to the manufacture or production of all spacecraft, notwithstanding the nature of the intended end use (e.g., even where the hardware is not SME), is designated SME.

Note to paragraph (f): The special export controls contained in § 124.15 of this subchapter are always required before a U.S. person may participate in a launch failure investigation or analysis and before the export of any article or defense service in this category for launch in, or by nationals of, a country that is not a member of the North Atlantic Treaty Organization or a major non-NATO ally of the United States. Such special export controls also may be imposed with respect to any destination as deemed appropriate in furtherance of the security and foreign policy of the United States.

PART 124—AGREEMENTS, OFFSHORE PROCURMENT AND OTHER DEFENSE SERVICES

3. The authority citation for Part 124 is revised 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.

4. Section 124.15 is revised to read as follows:

§ 124.15 Special Export Controls for Defense Articles and Defense Services Controlled under Category XV: Space Systems and Space Launches.

(a) The export of any satellite or related item (see § 121.1, Category XV(a) and (e)) or any defense service controlled by this subchapter associated with the launch in, or by nationals of, a country that is not a member of the North Atlantic Treaty Organization or a major non-NATO ally of the United States always requires special exports controls, in addition to other export controls required by this subchapter, as follows:

(1) All licenses and other requests for approval require a technology transfer control plan (TTCP) approved by the Department of Defense and an

encryption technology control plan approved by the National Security Agency. Drafts reflecting advance discussions with both agencies must accompany submission of the license application or proposed technical assistance agreement, and the letter of transmittal required in § 124.12 must identify the U.S. Government officials familiar with the preparation of the draft TTCPs. The TTCP must require any U.S. person or entity involved in the export to notify the Department of Defense in advance of all meetings and interactions with any foreign person or entity that is a party to the export and require such U.S. person or entity to certify that it has complied with this notification requirement within 30 days after launch.

(2) The U.S. person must make arrangements with the Department of Defense for monitoring. The costs of such monitoring services must be fully reimbursed to the Department of Defense by the U.S. person receiving such services. The letter of transmittal required under § 124.12 must also state that such reimbursement arrangements have been made with the Department of Defense and identify the specific Department of Defense official with whom these arrangements have been made. As required by Public Law 105–261, such monitoring will cover, but not be limited to—

(i) Technical discussions and activities, including the design, development, operation, maintenance, modification, and repair of satellites, satellite components, missiles, other equipment, launch facilities, and launch vehicles;

(ii) Satellite processing and launch activities, including launch preparation, satellite transportation, integration of the satellite with the launch vehicle, testing and checkout prior to launch, satellite launch, and return of equipment to the United States;

(iii) Activities relating to launch failure, delay, or cancellation, including post-launch failure investigations or analyses with regard to either the launcher or the satellite; and

(iv) All other aspects of the launch.

(b) Mandatory licenses for launch failure (crash) investigations or analyses: In the event of a failure of a launch from a foreign country (including a post liftoff failure to reach proper orbit)—

(1) The activities of U.S. persons or entities in connection with any subsequent investigation or analysis of the failure continue to be subject to the controls established under section 38 of the Arms Export Control Act, including the requirements under this subchapter

for express approval prior to participation in such investigations or analyses, regardless of whether a license was issued under this subchapter for the initial export of the satellite or satellite component;

(2) Officials of the Department of Defense must monitor all activities associated with the investigation or analyses to insure against unauthorized transfer of technical data or services and U.S. persons must follow the procedures set forth in paragraphs (a)(1) and (a)(2) of this Category.

(c) Although Public Law 105–261 does not require the application of special export controls for the launch of U.S.-origin satellites and components from or by nationals of countries that are members of NATO or major non-NATO allies, such export controls may nonetheless be applied, in addition to any other export controls required under this subchapter, as appropriate in furtherance of the security and foreign policy of the United States. Further, the export of any article or defense service controlled under this subchapter to any destination may also require that the special export controls identified in paragraphs (a)(1) and (a)(2) of this category be applied in furtherance of the security and foreign policy of the United States.

(d) Mandatory licenses for exports to insurance providers and underwriters: None of the exemptions or sub-licensing provisions available in this subchapter may be used for the export of technical data in order to obtain or satisfy insurance requirements. Such exports are always subject to the prior approval and re-transfer requirements of sections 3 and 38 of the Arms Export Control Act, as applied by relevant provisions of this subchapter.

Dated: March 11, 1999.

John D. Holm,

Acting Under Secretary of State for Arms Control and International Security Affairs and Director, U.S. Arms Control and Disarmament Agency, Department of State.
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