Vehicles and Related Equipment is amended by revising ECCN 9A004:

**9A004 Space launch vehicles and ''spacecraft''.**

**License Requirements**

Reason for Control: NS and AT

| Control(s) | Country chart |
|---|---|
| NS applies to entire entry ..... | NS Column 1 |
| AT applies to entire entry ..... | AT Column 1 |

**License Exceptions**

LVS: N/A
GBS: N/A
CIV: N/A

**List of Items Controlled**

Unit: Equipment in number. Components, parts and accessories in $ value. Related Controls: (1.) See also 9A104. (2.) Space launch vehicles are under the jurisdiction of the Department of State. (3.) Effective March 15, 1999, all satellites, including commercial communications satellites, are subject to the ITAR. Effective March 15, 1999, all license applications for the export of commercial communications satellites will be processed by the State Department, Office of Defense Trade Controls. Retransfer of jurisdiction for commercial communications satellites and related items shall not affect the validity of any export license issued by the Department of Commerce prior to March 15, 1999, or of any export license application filed under the Export Administration Regulations on or before March 14, 1999, and subsequently issued by the Department of Commerce. Commercial communications satellites licensed by the Department of Commerce, including those already exported, remain subject to the EAR and all terms and conditions of issued export licenses until their stated expiration date. All licenses issued by the Department of Commerce for commercial communications satellites, including licenses issued after March 15, 1999, remain subject to SI controls throughout the validity of the license. Effective March 15, 1999, Department of State jurisdiction shall apply to any instance where a replacement license would normally be required from the Department of Commerce. Transferring registration or operational control to any foreign person of any item controlled by this entry must be authorized on a license issued by the Department of State, Office of Defense Trade Controls. This requirement applies whether the item is physically located in the United States or abroad. (4.) All other ''spacecraft'' not controlled under 9A004 and their payloads, and specifically designed or modified components, parts, accessories, attachments, and associated equipment, including ground support equipment, are subject to the export licensing authority of the Department of State unless otherwise transferred to the Department of Commerce via a commodity jurisdiction determination by the Department of State. (5.) Exporters requesting a license from the Department of Commerce for ''spacecraft'' and their associated parts and components, other than the international space station, must provide a statement from the Department of State, Office of Defense Trade Controls, verifying that the item intended for export is under the licensing jurisdiction of the Department of Commerce. All specially designed or modified components, parts, accessories, attachments, and associated equipment for ''spacecraft'' that have been determined by the Department of State through the commodity jurisdiction process to be under the licensing jurisdiction of the Department of Commerce and that are not controlled by any other ECCN on the Commerce Control List will be assigned a classification under this ECCN 9A004. (6.) Technical data required for the detailed design, development, manufacturing, or production of the international space station (to include specifically designed parts and components) remains under the jurisdiction of the Department of State. This control by the ITAR of detailed design, development, manufacturing or production technology for NASA's international space station does not include that level of technical data necessary and reasonable for assurance that a U.S.-built item intended to operate on NASA's international space station has been designed, manufactured, and tested in conformance with specified requirements (e.g., operational performance, reliability, lifetime, product quality, or delivery expectations). All technical data and all defense services, including all technical assistance, for launch of the international space station, including launch vehicle compatibility, integration, or processing data, are controlled and subject to the jurisdiction of the Department of State, in accordance with 22 CFR parts 120 through 130.

*Items*

a. The international space station being developed, launched and operated under the supervision of the U.S. National Aeronautics and Space Administration. Hardware specific to the international space station transferred to the Department of Commerce by commodity jurisdiction action is also included.

b. Specific items as may be determined to be not subject to the ITAR through the commodity jurisdiction procedure administered by the Department of State after March 15, 1999.

Dated: March 15, 1999.

**R. Roger Majak,**

*Assistant Secretary for Export Administration.*

[FR Doc. 99–6721 Filed 3–16–99; 12:02 pm]

**BILLING CODE 3510–33–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 520

## Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble 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 Phoenix Scientific, Inc. The ANADA provides for oral use of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, cattle, swine, and sheep for the treatment and control of various bacterial diseases.

**EFFECTIVE DATE:** March 18, 1999.

**FOR FURTHER INFORMATION CONTACT:** Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–247 that provides for use of oxytetracycline hydrochloride soluble powder (343 grams of oxytetracycline hydrochloride per pound) in the drinking water of chickens, turkeys, cattle, swine, and sheep for the treatment and control of various bacterial diseases.

Approval of Phoenix Scientific, Inc.'s ANADA 200–247 oxytetracycline hydrochloride soluble powder-343 is as a generic copy of Pfizer, Inc.'s NADA 8–622 Terramycin-343 (oxytetracycline soluble powder). ANADA 200–247 is approved as of February 10, 1999, and the regulations are amended in § 520.1660d (21 CFR 520.1660d) by revising paragraph (a)(7) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, § 520.1660d is amended by removing paragraph (c) and redesignating paragraphs (d) and (e) as paragraphs (c) and (d).

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.

**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.

2. Section 520.1660d is amended by revising paragraph (a)(7), by removing paragraph (c), and by redesignating paragraphs (d) and (e) as paragraphs (c) and (d) to read as follows:

**§ 520.1660d Oxytetracycline hydrochloride soluble powder.**

(a) * * *

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

* * * * *

Dated: February 26, 1999.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 99–6532 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Parts 520, 556, and 558

## Animal Drugs, Feeds, and Related Products; Lincomycin

**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 three supplemental new animal drug applications (NADA's) filed by Pharmacia & Upjohn Co. The supplemental NADA's provide new tolerances and withdrawal times for use of lincomycin, and codification of an acceptable daily intake (ADI).

**EFFECTIVE DATE:** March 18, 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:** Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA's 34–025, 97–505, and 111–636. NADA 34–025 provides for use of Lincocin® sterile solution and Lincomix® injectable (lincomycin hydrochloride) for dogs, cats, and swine. NADA 97–505 provides for use of Lincomix® 20/50 Type A medicated articles and Lincomix® 10 Type B medicated feed (lincomycin hydrochloride) for swine and broiler chickens. NADA 111–636 provides for use of Lincomix® soluble powder (lincomycin hydrochloride) for swine and broiler chicken drinking water. The supplemental NADA's provide for establishing a zero withdrawal period for lincomycin oral products, establishing residue tolerances of 0.6 parts per million (ppm) in swine liver and 0.1 ppm in swine muscle, and establishing an ADI of 25 micrograms per kilogram of body weight per day. The supplemental NADA's are approved as of August 25, 1998, and the regulations in 21 CFR 520.1263c(d)(1)(i)(C), 556.360, and 558.325(c)(2)(ii)(*b*), (c)(2)(iii)(*b*), and (c)(2)(iv)(*b*) are amended to reflect the approval. The basis of approval is discussed in each freedom of information summary.

Since these approvals involve revised tolerances for residues of lincomycin in edible tissues of swine, § 556.360 is amended to reflect the revised tolerance for lincomycin residues in swine tissues.

In addition to revising the tolerance for lincomycin residues in swine tissues, FDA is further amending the tolerance regulation to codify the ADI for total residues of lincomycin. The ADI is the amount of total drug residue that can be safely consumed by humans every day.

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)), the supplemental approval for food-producing animals for Lincocin® sterile solution and Lincomix® injectable (NADA 34–025) qualifies for 3 years of marketing exclusivity beginning August 25, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new tolerance for lincomycin in swine liver for which the supplemental NADA was approved.

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 520*

Animal drugs.

*21 CFR Part 556*

Animal drugs, Foods.

*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 520, 556, and 558 are 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.

**§ 520.1263c [Amended]**

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (d)(1)(i)(C) by removing the last sentence.